CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Abbreviated Analysis

California Senate Bill 853: Prescription Drug Coverage

Summary to the 2021–2022
California State Legislature
April 5, 2022

Prepared by
California Health Benefits Review Program
www.chbrp.org

Suggested Citation: *California Health Benefits Review Program (CHBRP). Abbreviated Analysis: California Senate Bill 853: Prescription Drug Coverage. Berkeley, CA: CHBRP; 2022.*

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 (SB) 853, Prescription Drug Coverage.

SB 853 would create a new health insurance benefit mandate and would amend two existing mandates.

SB 853 would create the Under Review Coverage mandate. It would require policies and plans regulated by the California Department of Insurance (CDI) or the Department of Managed Health Care (DMHC) that include a pharmacy benefit to provide coverage for a drug or dose of a drug, or dosage form (for example, oral vs. injectable) of a drug prescribed by a health care provider — if that drug has been previously approved for coverage by a policy/plan for an enrollee's medical condition — during the entire duration of utilization review and any appeals of utilization review.

An existing mandate, the Off-Label mandate, requires that CDI-regulated policies and DMHC-regulated plans that include a pharmacy benefit not exclude a drug from coverage because the drug is being prescribed for a non-approved FDA indication when (1) the drug is prescribed by a contracting prescriber and (2) when specified criteria are met. Required coverage includes any medically necessary services associated with the administration of the drug. SB 853 would amend the Off-Label mandate to also address dose of a drug or dosage form. The existing mandate exempts from compliance plans enrolling Medi-Cal beneficiaries, as would the amended mandate.

Another existing mandate, the Continuity mandate, is directly applicable to DMHC-regulated plans that include a pharmacy benefit. Due to its incorporation by reference in the Insurance Code,[2] it also applies to nongrandfathered individual and small-group health insurance policies. The mandate requires that plans 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. Generic substitution is allowed. SB 853 would amend the Continuity mandate to also address dose of a drug, or dosage form. SB 853 would also amend the Continuity mandate to make clear that it would not be applicable to drugs, doses of drugs, or dosage forms of drugs denied coverage after a final utilization review pursuant to the new Under Review Coverage mandate.

Background. Plans and policies that include a pharmacy benefit may apply utilization management techniques (including prior authorization, step therapy, and formulary requirements). 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. The period when a plan or insurer is considering the prior authorization request is one stage of what SB 853 refers to as utilization review. 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).

Analytic Approach. For analysis of the new Under Review Coverage mandate, CHBRP has assumed that SB 853's reference to "utilization review and any appeals of utilization review" would include as many as three periods:

- Prior authorization review and response by the plan or insurer

[1] Refer to CHBRP's full report for full citations and references.
[2] Insurance Code section 10112.27(a)(2)(A)(iv)

- Appeal review and response by the plan or insurer
- Appeal review and response by the regulator (DMHC or CDI)

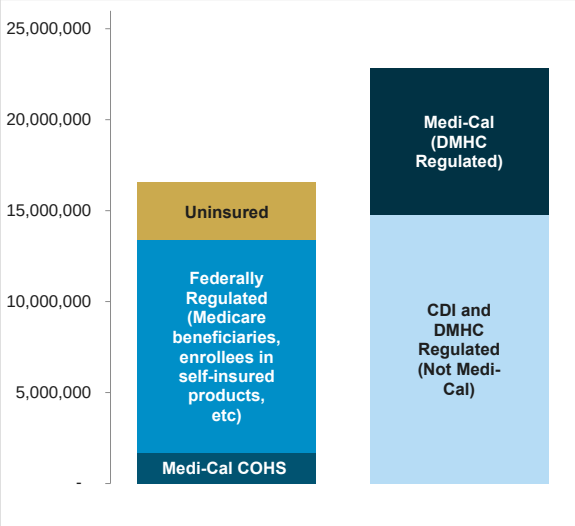
After what would generally be 1-3 script fills during these three periods, utilization management techniques would be applicable, which would limit further impact of the Under Review Coverage mandate.

CHBRP has assumed that the additional scripts filled required by SB 853 would be for a 30-day supply.

As the number of outpatient prescription drugs for which SB 853 could change access to coverage would be extremely large, no analysis of medical effectiveness could be completed within CHBRP's 60-day analytic period. However, this abbreviated analysis presents SB 853's expected impacts on benefit coverage, utilization, and cost.

Figure A describes sources of health insurance for all Californians.

Figure A. Health Insurance in CA



Source: California Health Benefits Review Program, 2022.

Benefit coverage. Medi-Cal beneficiaries enrolled in DMHC-regulated plans have a pharmacy benefit but not one that is included their DMHC-regulated plan. The mandates included in SB 853 do not require creation of a pharmacy benefit — only compliant coverage when a pharmacy benefit regulated by DMHC or CDI is present — so these enrollees have benefit coverage that is (1) compliant with the existing Off-Label and Continuity mandates, (2) compliant with these two mandates as SB 853 would amend them, and (3) compliant with the Under Review Coverage mandate SB 853 would create. The same is true for the approximately 5% of commercial and CalPERS enrollees in policies and plans regulated by CDI and/or DMHC that are without a pharmacy benefit regulated by CDI or DMHC. Of the remaining commercial/CalPERS enrollees, at baseline, none have benefit coverage that is fully compliant with SB 853. Postmandate, all would.

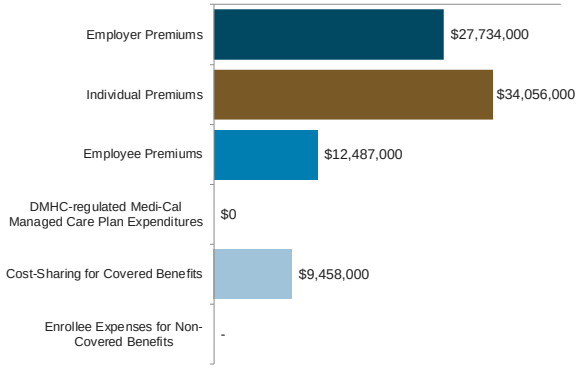
Utilization. At baseline, the total annual number of scripts filled for drugs impacted by SB 853 (predominantly maintenance drugs with utilization review requirements) is 1,108,750. This figure represents less than 1% of scripts filled for enrollees with a pharmacy benefit regulated by DMHC or CDI. Postmandate, 22,851 additional scripts would be filled. This impact would primarily derive from the Under Review Coverage mandate, which would influence coverage for enrollees changing one plan or policy for another, a situation often referred to as enrollee "churn."

Unit Cost. At baseline, the average unit cost of a 30-day supply for a drug with coverage impacted by SB 853 that will ultimately be approved is estimated to be $1,336. Within this average, unit costs for particular drugs range from less than $50 to more than $6,000. Postmandate, the average unit cost would be higher, not because the unit costs of the drugs would change, but because the mix of covered script fills would include greater proportions of specialty and brand drugs, which are generally more expensive.

Expenditures. As noted in Figure B, SB 853 would increase total net annual expenditures by $83,735,000 (0.06%) for enrollees with health insurance subject to state-level benefit mandates. This is due to a $74,277,000 increase in total health insurance premiums and a $9,458,000 increase in enrollee cost sharing. CHBRP projects 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 specialty and brand drugs, as well as off-

formulary drugs (which are often associated with greater per-fill cost sharing) and therefore an increase in total enrollee cost sharing.

Figure B. Expenditure Impacts of SB 853



Source: California Health Benefits Review Program, 2022.

At baseline, an unknown proportion of noncovered script fills may have been accessed by enrollees through self-pay. Given the high cost of many drugs impacted by SB 853, this proportion may be limited by the willingness of enrollees to self-pay for high-cost drugs. Postmandate, such expenses would decrease (though there would be a concomitant increase in cost sharing).

Number of Uninsured in California. The impacts of SB 853 on expenditures would not be great enough to expect any change in the number of uninsured.

Essential Health Benefits. As SB 853 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 853 on Benefit Coverage, Utilization, and Cost, 2023

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Enrollees with health insurance subject to state benefit mandates (a)	22,810,000	22,810,000	0	0.00%
Enrollees with health insurance subject to Under Review Coverage mandate (b)	22,810,000	22,810,000	0	0.00%
Enrollees with health insurance coverage fully compliant with Under Review Coverage mandate	8,755,000	22,810,000	14,055,000	160.54%
Enrollees with health insurance subject to Off-Label mandate (c)	14,776,000	14,776,000	0	0.00%
Enrollees with health insurance coverage fully compliant with Off-Label mandate	721,000	14,776,000	14,055,000	1949.38%
Enrollees with health insurance subject to Continuity mandate (d)	22,325,000	22,325,000	0	0.00%
Enrollees with health insurance coverage fully compliant with Continuity mandate	8,730,000	22,325,000	13,595,000	155.73%
Utilization and unit cost				
Number of Impacted Scripts Filled (e)	1,108,750	1,131,601	22,851	2.06%
Average Unit Cost of Impacted Scripts Filled (e)	$1,336	$1,372	$36	2.67%
Expenditures				
Premiums (expenditures) by payer				
Private employers for group insurance	$52,967,575,000	$52,994,566,000	$26,991,000	0.05%
CalPERS HMO employer expenditures (f) (g)	$5,895,476,000	$5,896,219,000	$743,000	0.01%
Medi-Cal Managed Care Plan expenditures (h)	$25,989,411,000	$25,989,411,000	$0	0.00%
Enrollee premiums (expenditures)				
Enrollees with individually purchased insurance	$24,029,788,000	$24,063,844,000	$34,056,000	0.14%
Individually purchased – outside Exchange	$6,324,312,000	$6,335,737,000	$11,425,000	0.18%
Individually purchased – Covered California	$17,705,476,000	$17,728,107,000	$22,631,000	0.13%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (g)	$24,504,936,000	$24,517,423,000	$12,487,000	0.05%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	$15,807,011,000	$15,816,469,000	$9,458,000	0.06%

Expenses for noncovered benefits (i)	-	-	-	-
Total expenditures	$149,194,197,000	$149,277,932,000	$83,735,000	0.06%

Source: California Health Benefits Review Program, 2022.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[3]

(b) SB 853 would create the Under Review Coverage mandate. It would require policies and plans regulated by the California Department of Insurance (CDI) or the Department of Managed Health Care (DMHC) that include a pharmacy benefit to provide coverage for a drug or dose of a drug, or dosage form (for example, oral vs. injectable) of a drug prescribed by a health care provider — if that drug has been previously approved for coverage by a policy/plan for an enrollee's medical condition — during the entire duration of utilization review and any appeals of utilization review.

(c) An existing mandate, the Off-Label mandate, requires that CDI-regulated policies and DMHC-regulated plans that include a pharmacy benefit not exclude a drug from coverage because the drug is being prescribed for a non-approved FDA indication when (1) the drug is prescribed by a contracting prescriber and (2) when specified criteria are met. Required coverage includes any medically necessary services associated with the administration of the drug. SB 853 would amend the Off-Label mandate to also address dose of a drug or dosage form. The existing mandate exempts from compliance plans enrolling Medi-Cal beneficiaries, as would the amended mandate.

(d) Another existing mandate, the Continuity mandate, is directly applicable to DMHC-regulated plans that include a pharmacy benefit. Due to its incorporation by reference in the Insurance Code, It also applies to nongrandfathered individual and small-group health insurance policies. The mandate requires that plans 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. Generic substitution is allowed. SB 853 would amend the Off-Label mandate to also address dose of a drug, or dosage form. SB 853 would also amend the Continuity mandate to make clear that it would not be applicable to drugs, doses of drugs, or dosage forms of drugs denied coverage after a final utilization review pursuant to the new Under Review Coverage mandate.

(e) The impacted scripts filled by SB 853 consist of two types of drugs. There would be an increase in scripts filled for maintenance drugs with prior authorization requirements, which are typically higher-cost specialty and brand drugs. There would be a concomitant decrease in scripts filled for alternative drugs with less stringent utilization review requirements.

(f) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.[4] 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).

(g) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(h) Includes only expenditures related to Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(i) 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 includes only 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 853, at baseline some enrollees would have self-paid for scripts filled for which coverage would have been denied. However, others would 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; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations.

[3] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2023*, a resource available at http://chbrp.org/other_publications/index.php.
[4] For more detail, see CHBRP's *Estimates of Pharmacy Benefit Coverage in California for 2023*, a resource available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[5] conduct an evidence-based assessment of SB 853, Prescription Drug Coverage.

Background

For enrollees in plans and policies regulated by the Department of Health Care Services (DMHC) or the California Department of Insurance (CDI), SB 853 would alter pharmacy benefit coverage.

Almost all enrollees in plans and policies regulated by DMHC and CDI have pharmacy benefit coverage.[6] 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. See Appendix C for further discussion of these techniques. 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, for instance 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. The period when a plan or insurer is considering the prior authorization request is one stage of what SB 853 refers to as utilization review. 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.[7] 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.[8,9] 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. Although submissions of appeals to regulators generally follow a second denial by the plan or insurer, it is possible to submit simultaneous appeals (one to the plan or insurer at the same time that another is submitted to the regulator). The regulator may uphold the denial or may require the plan or insurer to cover the drug.

[5] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[6] 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 for 2023*, available at https://chbrp.org/other_publications/index.php.
[7] H&S 1367.241, INS 10123.191.
[8] H&S code 1368.
[9] 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).

Bill Language

SB 853 would create a new health insurance benefit mandate and would amend two existing mandates.

SB 853 would create the Under Review Coverage mandate. It would require policies and plans regulated by the California Department of Insurance (CDI) or the Department of Managed Health Care (DMHC) that include a pharmacy benefit to provide coverage for a drug or dose of a drug, or dosage form (for example, oral vs. injectable) of a drug prescribed by a health care provider — if that drug has been previously approved for coverage by a policy/plan for an enrollee's medical condition — during the entire duration of utilization review and any appeals of utilization review.

An existing mandate, the Off-Label mandate, requires that CDI-regulated policies and DMHC-regulated plans that include a pharmacy benefit not exclude a drug from coverage because the drug is being prescribed for a non-approved FDA indication when (1) the drug is prescribed by a contracting prescriber and (2) when specified criteria are met. Required coverage includes any medically necessary services associated with the administration of the drug. SB 853 would amend the Off-Label mandate to also address dose of a drug or dosage form. The existing mandate exempts from compliance plans enrolling Medi-Cal beneficiaries, as would the amended mandate.

Another existing mandate, the Continuity mandate, is directly applicable to DMHC-regulated plans that include a pharmacy benefit. Due to its incorporation by reference in the Insurance Code,[10] it also applies to nongrandfathered individual and small-group health insurance policies. The mandate requires that plans 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. Generic substitution is allowed. SB 853 would amend the Continuity mandate to also address dose of a drug, or dosage form. SB 853 would also amend the Continuity mandate to make clear that it would not be applicable to drugs, doses of drugs, or dosage forms of drugs denied coverage after a final utilization review pursuant to the new Under Review Coverage mandate.

The full text of SB 853 can be found in Appendix A.

Analytic Approach and Key Assumptions

For this analysis CHBRP has assumed that mandates that reference plans and policies that cover prescription drugs, such as the mandates addressed by SB 853, 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), along with the hospital stay or office visit, are generally covered through a medical benefit. Pharmacy benefits cover outpatient prescription drugs by covering scripts that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy.

For this analysis, for consideration of the new Under Review Coverage mandate, CHBRP has assumed that "utilization review and any appeals of utilization review" would include as many as three periods:

- Prior authorization review and response by the plan or insurer
- Appeal review and response by the plan or insurer
- Appeal review and response by the regulator (DMHC or CDI)

After what would generally be 1-3 script fills during these three periods, utilization management techniques would be applicable, which would limit the further impact of the Under Review Coverage mandate.

[10] Insurance Code section 10112.27(a)(2)(A)(iv).

For all three mandates, CHBRP has assumed that:

- The benefit coverage of enrollees without a pharmacy benefit regulated by CDI or DMHC would be compliant.
- A generic-only pharmacy benefit regulated by CDI or DMHC would not be required to cover brand-name drugs.

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 853 would amend California's existing Off-Label and Continuity mandates.

CHBRP is unaware of any California law or regulation similar to the new Under Review Coverage mandate SB 853 would create.

All three SB 853 mandates would interact with existing California laws that address plan and insurer turn-around time. 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.[11]
- An appeal — generally within 30 calendar days (or faster in emergency circumstances).[12,13]

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, 2022). Bills that would create Off-Label and/or Continuity mandates are (or were recently) under consideration in three other states.

- Florida S 564 / H 633 would prohibit insurers or HMOs from excluding coverage in any individual or group health insurance policy or health maintenance contract that covers cancer treatment for any drug prescribed for cancer treatment on the ground that the drug is not approved by the FDA for a certain indication, if that drug is recognized for treatment of that indication in a standard reference compendium or recommended in the medical literature.

[11] H&S 1367.241, INS 10123.191.
[12] 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).
[13] 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.

- Florida S 1100 would require insurers to authorize coverage for prescribed drugs based solely on the treating physician's certification that the drug is medically necessary.
- Iowa H 2199 would prohibit plans and insurers organizations from limiting or excluding prescription drug coverage for any enrollee who is medically stable on such drug, if (1) the drug was previously approved by the plan/insurer for coverage for the enrollee, (2) the enrollee was prescribed the drug within the last six months, and (3) the enrollee continues to be enrolled in the health benefit plan. Generic substitutions would be allowed.
- New Jersey S 1182 would require prescription drug coverage for enrollees with complex/chronic medical conditions or rare diseases, if (1) the drug was previously covered for a condition/disease of the enrollee, and (2) the prescribing provider continues to prescribe the drug for the condition/disease, provided the drug is appropriately prescribed and the FDA has not called into question the drug's clinical safety.

Federal Policy Landscape

Similar requirements for Medicare Prescription Drug Benefit (Part D) beneficiaries

Although it does not address dose or dosage form, to promote continuity of care and avoid interruption, Medicare does require transition coverage of off-formulary Part D drugs for beneficiaries prescribed the drugs as ongoing therapy with that drug (CMS, 2016). Transitions include changes of formulary by the Part D sponsor and changes in Part D sponsor by the beneficiary. Coverage for one 30-day transition fill is available for the first 90 days after an enrollee switches plans. Generally, Part D sponsors can apply prior authorization or step therapy requirements after the transition fill.

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 853 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).[14,15]

In California, nongrandfathered[16] individual and small-group health insurance is generally required to cover essential health benefits (EHBs).[17] In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.[18]

As SB 853 would not require coverage for a new benefit mandate, the bill would not appear to exceed the definition of EHBs in California.

[14] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs 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.
[15] 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.
[16] 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.
[17] 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.
[18] 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: An Update and Overview of New Federal Regulations*, 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 853 could change access to coverage would be extremely large. An analysis of medical effectiveness for the 600 drugs (Jones et al., 2020) for which prior authorization requirements are often present could not be completed within CHBRP's 60-day analytic period. However, this abbreviated analysis presents SB 853's expected impacts on benefit coverage, utilization, and cost.

For this analysis, CHBRP has assumed that the additional scripts filled, postmandate, would be for a 30-day supply, even if the review period for a prior authorization request may be as short as 24 or 72 hours. For maintenance drugs — the drugs for which coverage would be predominantly affected by SB 853 — prescribers typically write prescriptions for a 30-day or 90-day supply. Standard 30-day packaging already exists for many maintenance drugs, and it would be administratively burdensome for the pharmacy to break such packages to dispense fewer-days supply. Additionally, CHBRP is aware that Medicare beneficiaries have coverage for a transition fill — a 30-day supply of drugs not on a new formulary — allowing prescribers and beneficiaries sufficient time to find a new drug if coverage for the prescribed drug were to be denied (NCOA, 2020). CHBRP assumes plans and insurers would follow a similar pattern to comply with SB 853.

The Under Review Coverage mandate would allow an enrollee coverage for several filled scripts filled for the same prescription written (coverage that would have been denied at baseline). For example:

- If a prescriber submitted a prior authorization for a drug meeting the requirements of SB 853, the enrollee could obtain coverage for one script filled.
- If the prior authorization were to be denied and the prescriber or enrollee submitted an appeal to the plan or insurer, the enrollee could obtain coverage for a second script filled.
- If the appeal to the plan/insurer were to be denied and the prescriber or enrollee submitted an appeal to the regulator, the enrollee could obtain coverage for a third script filled.

However, as SB 853 would not prohibit application of utilization management techniques (including prior authorization, step therapy, and formulary requirements). Application of these techniques subsequent to script fills required by SB 853 (during review of prior authorization requests and appeals) would limit the impact of SB 853.

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

Baseline and Postmandate Benefit Coverage

As noted in Table 2, the mandates SB 853 would create or amend vary as to which enrollees have benefit coverage that must comply.

Table 2. Applicability of SB 853 Mandates

	Applicable to the Benefit Coverage of		
	Enrollees in CDI-Regulated Policies	Commercial/CalPERS Enrollees in DMHC-Regulated Plans	Medi-Cal Beneficiaries Enrolled in DMHC-Regulated Plans
New Under Review Coverage Mandate	Yes	Yes	Yes
Existing/Amended Off-Label Mandate	Yes	Yes	No
Existing/Amended Continuity Mandate	Partial*	Yes	Yes

Source: California Health Benefits Review Program, 2022.

Notes: *Applies only to the benefit coverage of enrollees in nongrandfathered small-group and individual market policies.

Currently, there are 22,810,000 enrollees in policies and plans regulated by CDI and/or DMHC whose benefit coverage would be subject to SB 853. As noted in Table 1 and Table 2, each of the three mandates apply to the benefit coverage of slightly different sets of these enrollees.

- 22,810,000 enrollees have benefit coverage that would be subject to the Under Review Coverage mandate.
- 14,776,000 enrollees have benefit coverage that would be subject to the Off-Label mandate. This is all enrollees less Med-Cal beneficiaries enrolled in DMHC-regulated plans.
- 22,325,000 enrollees have benefit coverage that would be subject to the Continuity mandate. This is all enrollees less enrollees in CDI-regulated large-group policies.

Among the sets of enrollees described above, impacts of SB 853 would only be seen among enrollees whose DMHC-regulated plan or CDI-regulated policy currently includes a pharmacy benefit (for the coverage of outpatient prescription drugs).

As previously noted, approximately 5% of commercial and CalPERS enrollees in policies and plans regulated by CDI and/or DMHC are without a pharmacy benefit regulated by CDI or DMHC.[19] The mandates included in SB 853 do not require creation of a pharmacy benefit — only compliant coverage when a pharmacy benefit regulated by CDI or DMHC is present — so these enrollees have benefit coverage that is (1) compliant with the existing Off-Label and Continuity mandates, (2) compliant with these two mandates as SB 853 would amend them, and (3) compliant with the Under Review Coverage mandate SB 853 would create.

Medi-Cal beneficiaries enrolled in DMHC-regulated plans do not have a DMHC-regulated pharmacy benefit. As of January 2022, coverage for prescription drugs has been carved out of the Medi-Cal managed care contracts. Therefore, like the 5% of commercial/CalPERS enrollees discussed above, these enrollees have benefit coverage that is (1) compliant with the existing Continuity mandate, (2) compliant with the Continuity mandate as SB 853 would amend it, and (3) compliant with the Under

[19] 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 for 2023*, available at https://chbrp.org/other_publications/index.php.

Review Coverage mandate SB 853 would create. The existing Off-Label mandate exempts from compliance the benefit coverage of Medi-Cal beneficiaries enrolled in DMHC-regulated plans and SB 853 would not end the exemption.

Of the remaining commercial/CalPERS enrollees, at baseline, none have benefit coverage that is fully compliant with SB 853. Postmandate, as noted in Table 1, the number of enrollees with benefit coverage that would change varies among the three mandates included in SB 853.

Baseline and Postmandate Utilization

In most circumstances, SB 853 would impact the coverage of prescription drugs when utilization review techniques (including prior authorization, step therapy, and formulary requirements) are present. Maintenance drugs with utilization review requirements are expected to be the predominant types of outpatient drugs for which utilization would be impacted by the three mandates.[20] At baseline, 6% of enrollees in commercial plans utilize such drugs.

For SB 853, baseline utilization figures (see Table 1) provide the number of 30-day scripts filled that would be impacted by any of the three mandates.

At baseline, the total number of scripts filled for drugs impacted by SB 853 — predominantly maintenance drugs with utilization review requirements — is 1,108,750. This figure is less than 1% of scripts filled for enrollees with a pharmacy benefit regulated by DMHC or CDI that would be impacted by SB 853. Postmandate, 22,851 additional scripts are projected to be filled (see Table 1).

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:

- The three mandates would prompt some increase in the number of scripts written and therefore filled. Postmandate, knowing that the mandates would require coverage, prescribers would be more willing to prescribe modifications to dose and dosage forms, and to submit prior authorization requests.
- At baseline, scripts written that are ultimately denied may result in scripts filled for alternative drugs (drugs subject to less rigorous utilization management than the drug for which coverage was denied) or in no scripts filled. The Under Review Coverage mandate would allow an enrollee to access limited scripts filled for these drugs under specified circumstances, even if coverage for the drug is ultimately denied. Postmandate, these scripts filled would be covered by plans and insurers for one or more 30-day fills. Although the addition of dose and dosage form to the Off-Label mandate and the Continuity mandate could require additional scripts filled for some enrollees, such situations would, on a statewide level, be less common than instances where enrollees accessed coverage through the Under Review Coverage mandate.[21] Therefore, the Under Review Coverage mandate would be the predominant factor impacting postmandate changes in utilization.
- For the Under Review Coverage mandate, an enrollee would have had to have approval for the drug from a previous plan or policy. This could only occur if an enrollee changed from one plan or policy to another plan or policy. Therefore, enrollee churn — that is, enrollees switching into a new plan or policy — would result in access to limited scripts filled under SB 853. For instance, this could include drugs that were on formulary for the prior plan or policy but are off-formulary for the new plan or policy.
- For the Under Review Coverage mandate, the mandate would also allow enrollees to fill scripts earlier, prior to the end of any period of utilization review or appeal. At baseline, up to 25% of enrollees do not obtain a first script filled following a prescription written (Fischer et al., 2011). CHBRP expects that earlier access would alter the behavior of some of these enrollees and so would increase overall utilization.

[20] Personal communication, J. Watanabe, March 18, 2022.
[21] Personal communication, J. Watanabe, March 18, 2022.

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 853 that will ultimately be approved is estimated to be $1,670. Within this average, unit costs for particular drugs range from less than $50 to more than $6,000.

Postmandate, the average unit costs of impacted scripts would be 2.67% 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 drugs and a greater proportion of specialty and brand drugs, which are generally more expensive. The postmandate mix of covered scripts would also include a greater proportion off-formulary drugs, which are less likely to have manufacturer rebates associated with them (CHBRP, 2022) and so are likely to have higher net costs for plans and insurers.[22]

Baseline and Postmandate Expenditures

SB 853 would increase total net annual expenditures by $83,735,000, or 0.06%, for enrollees with health insurance subject to state-level benefit mandates. This is due to a $74,277,000 increase in total health insurance premiums and a $9,458,000 increase in enrollee cost sharing.

Table 3 and Table 4 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, and total expenditures (premiums as well as enrollee expenses).

The impacts presented in Table 1 and Table 4 are related to the number of enrollees expected to use, during the first postmandate year, outpatient prescription drugs for which utilization management techniques (including prior authorization, step therapy, and formulary requirements) would be applicable.

Impacts presented in Table 1 and Table 4 are statewide figures. In great part because the presence of utilization management techniques (including prior authorization, step therapy, and formulary requirements) varies from plan to plan and policy to policy, the impacts that make up these statewide figures vary from plan to plan and from policy to policy, as well as between market segments. As discussed above, the impact would also vary due to churn, which also varies between market segments.

Premiums

Changes in premiums as a result of SB 853 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 3, and Table 4) with health insurance that would be subject to SB 853.

Total premiums for private employers purchasing group health insurance would increase by $26,991,000, or 0.05%. Total premiums for purchasers of individual market health insurance would increase by $34,056,000, or 0.14%. The greatest change in premiums as a result of SB 853 is for the individual policies (0.26% increase) in the CDI-regulated market. This is driven by the higher churn for individual market as well as the generally more present and more stringent utilization management techniques applied for individual market plans and policies.

Total premiums for DMHC-regulated Medi-Cal managed care plans would not be impacted by SB 853 because all of these Medi-Cal beneficiaries have a pharmacy benefit that is not regulated by DMHC.

Total premiums for CalPERS HMOs would increase by 0.01%.

[22] Personal communication, J. Watanabe, March 18, 2022.

Enrollee Expenses

SB 853–related changes in total cost sharing for covered benefits (deductibles, copays, etc.) would vary by market segment.

CHBRP projects 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 specialty drugs, brand drugs, and off-formulary drugs (which are often associated with higher copays) and therefore an increase in enrollee cost sharing. For the additional scripts filled under SB 853, cost sharing would be similar to average cost sharing (or average coinsurance) for a typical plan design within each metal level[23] or deductible level limited by the maximum cost sharing as defined by applicable California law.[24]

Note that cost sharing for prescription drugs, like the use of utilization management techniques, 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 853, at baseline, noncovered drugs may be frequently forgone by enrollees (or alternative drugs with less stringent prior authorization requirements 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 853 on cost sharing and enrollee expenses for noncovered benefits would vary depending on a number of factors including the ultimate denial or approval of the drug, applicable cost sharing, as well as an enrollee's choice to self-pay for noncovered benefits. Therefore, enrollees may experience very different enrollee expense impact, as the examples below demonstrate.

> **Example 1: No cost sharing change.** Despite a change in coverage for an enrollee, SB 853 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 using (e.g., switching from an oral form to an injectable), which triggers a utilization review. The review results in an approval. At baseline, the enrollee (not willing to self-pay) waits until the pharmacy receives the utilization review decision to fill the script. Postmandate, the enrollee would fill the script for the new dosage form with no interruption during the utilization review 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 2: Increase in cost sharing.** For other enrollees, SB 853 may result in a cost sharing increase. Consider an enrollee who has also routinely filled an ongoing monthly prescription for a brand maintenance drug, paying a $100 copay for each monthly script filled. This enrollee

[23] 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.

[24] 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.

switches from one plan or policy to another. The drug is not on formulary for the new plan or policy, which triggers a utilization review. The review results in a denial. The prescriber then submits a prior authorization request, triggering a second utilization review. The second review upholds the denial. At baseline, the enrollee (not willing to self-pay) would switch to a drug covered by the new plan or policy. Postmandate, the enrollee would have coverage for one script filled while the new plan or insurer reviews the prior authorization request. The applicable cost sharing for an off-formulary drug could be as high as $250. In this example, the enrollee would experience as much as a $150 increase in cost sharing for one fill.

Example 3: Decrease in enrollee's total expense. For still other enrollees, SB 853 may result in an increase in cost sharing but also a decrease in self-pay such that the enrollee's total expense would decrease. Consider an enrollee who has routinely filled an ongoing monthly script for a brand maintenance drug, paying a $100 copay for each monthly script filled. This enrollee switches from one plan or policy to another. The drug is on formulary for the new plan or policy but is subject to utilization review by the new plan or policy. The review results in a denial. The prescriber then submits a prior authorization request, triggering a second utilization review. The second review upholds the denial. At baseline, the enrollee choses to self-pay for the drug, which costs $2,000. Postmandate, while the new plan or insurer reviews the prior authorization request, the enrollee would have coverage for one script filled. If new plan or policy applies similar cost sharing rules as the old one, the copay would be $100. In this example, the enrollee's cost sharing increases by $100 but the enrollee's self-pay expense decreases by $2,000, a net decrease of $1,900.

Example 2 and example 3 describe a postmandate change for one script filled for a maintenance drug — drugs for which scripts are generally filled every month throughout the year. After the covered fills required during utilization review and appeal, (the number depending on the enrollee's use of prior authorization requests and appeals to the plan/insurer), utilization management would likely affect the remainder of the year's scripts filled, limiting the further impact of SB 853.

An enrollee could extend the effects described in examples 2 and 3 for a fill or two by submitting an appeal to the appropriate regulator. However, unless the denial related to the prior authorization request was overturned, the effect would not extend to all of the remaining scripts that would be filled during the year.

In all of these examples, the presence of a deductible not yet met for the year[25] could result in the enrollee paying the full unit cost, but hitting the annual out-of-pocket maximum[26] would result in the enrollee having no further cost sharing.

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 the drug covered under their prior plan or policy and so do not fill a script for an alternative drug (one with less stringent prior authorization requirements). However, as the postmandate filled scripts are frequently for brand or specialty drugs, which generally have higher unit cost, average unit cost would still increase postmandate.

[25] 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.
[26] 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.

Another type of offset is also possible, though would not be expected to occur often. An enrollee could respond better to a previously covered drug than to an alternative drug (one with less stringent prior authorization requirements) and so have improved health outcomes and reduced use of healthcare services. However, the SB 853 mandates do not prohibit plans and insurers from utilization management. CHBRP has projected that SB 853 would allow enrollees access to coverage for one to three script fills, but that utilization management would, in most cases, prompt the enrollee to then move to the alternative drug. This would be similar to the experience of Medicare beneficiaries, whose Part D pharmacy benefit providers cover a transition fill when a beneficiary moves from one plan or policy to another. Medicare Part D transition fills have increased temporary access to previously prescribed drugs (Afendulis et al., 2011), but CHBRP is unaware of any evidence linking transition scripts filled to measurable impacts on utilization of other health care services. 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 other health care services offsets as a result of what will usually be a one-to-three fill change for a maintenance drug.

Postmandate Administrative Expenses and Other Expenses

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

Due to the existence of transition fill requirements for Medicare, the National Council for Prescription Drug Programs (NCPDP) has already provided specifications for pharmacy transactions where a drug was previously approved by another plan.

Other Considerations for Policymakers

Changes in Public Program Enrollment

SB 853 would not require change for enrollees without a pharmacy benefit regulated by DMHC or CDI. Therefore, no impact would be expected among Medi-Cal beneficiaries enrolled in DMHC-regulated plans (for whom the pharmacy benefit is carved out and covered by DHCS). Similarly, no impact would be expected for CalPERS enrollees for whom the pharmacy benefit has been carved out of their DMHC-regulated plan. Therefore, CHBRP estimates that SB 853 would produce no measurable impact on enrollment in publicly funded insurance programs.

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

The second-year impacts of SB 853 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures may occur due to population changes between the first year postmandate and the second year postmandate.

Table 3. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to SB 853	8,317,000	2,125,000	2,758,000	881,000	0	0	485,000	44,000	166,000	14,776,000
Premiums										
Average portion of premium paid by employer	$407.24	$369.14	$0.00	$557.65	$238.69	$521.94	$465.60	$379.33	$0.00	$84,852,462,000
Average portion of premium paid by employee	$166.59	$204.69	$691.58	$113.48	$0.00	$0.00	$228.48	$246.41	$572.88	$48,534,724,000
Total premium	$573.83	$573.83	$691.58	$671.13	$238.69	$521.94	$694.08	$625.74	$572.88	$133,387,186,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$48.46	$124.44	$175.87	$58.77	$0.00	$0.00	$146.18	$200.65	$200.15	$15,807,011,000
Expenses for noncovered benefits (e)	--	--	--	--	--	--	--	--	--	--
Total expenditures	$622.29	$698.27	$867.45	$729.89	$238.69	$521.94	$840.26	$826.39	$773.02	$149,194,197,000

Source: California Health Benefits Review Program, 2022.

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

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC. 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) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) 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 includes only 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 853, at baseline some enrollees would have self-paid for scripts filled for which coverage would have been denied. However, others would 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.

.

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

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

Table 4. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to SB 853	8,317,000	2,125,000	2,758,000	881,000	0	0	485,000	44,000	166,000	14,776,000
Premiums										
Average portion of premium paid by employer	$0.1720	$0.2807	$0.0000	$0.0704	$0.0000	$0.0000	$0.4213	$0.4182	$0.0000	$27,735,000
Average portion of premium paid by employee	$0.0703	$0.1556	$0.9395	$0.0143	$0.0000	$0.0000	$0.2067	$0.2717	$1.4859	$46,542,000
Total premium	$0.2423	$0.4363	$0.9395	$0.0847	$0.0000	$0.0000	$0.6280	$0.6899	$1.4859	$74,276,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$0.0209	$0.0520	$0.1331	$0.0074	$0.0000	$0.0000	$0.1325	$0.1144	$0.3666	$9,458,000
Expenses for noncovered benefits (e)	--	--	--	--	--	--	--	--	--	--
Total expenditures	$0.2632	$0.4882	$1.0726	$0.0921	$0.0000	$0.0000	$0.7605	$0.8043	$1.8525	$83,735,000
Percent change										
Premiums	0.0422%	0.0760%	0.1359%	0.0126%	0.0000%	0.0000%	0.0905%	0.1103%	0.2594%	0.0557%
Total expenditures	0.0423%	0.0699%	0.1237%	0.0126%	0.0000%	0.0000%	0.0905%	0.0973%	0.2396%	0.0561%

Source: California Health Benefits Review Program, 2022.

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

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC. 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) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) 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 includes only 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 853, at baseline some enrollees would have self-paid for scripts filled for which coverage would have been denied. However, others would 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.

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

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

.

APPENDIX A TEXT OF BILL ANALYZED

On February 4, 2022, the California Senate Committee on Health requested that CHBRP analyze SB 853. On February 23, 2022, the Committee asked CHBRP to analyze proposed language changes which were included in the February 28, 2022, amendments to the bill.

AMENDED IN SENATE FEBRUARY 28, 2022

SENATE BILL **NO. 853**

Introduced by Senator Wiener

January 19, 2022

An act to amend Sections 1367.21 and 1367.22 of, and to add Section 1367.28 to, 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 853, 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 prohibit limiting or excluding coverage of a dose of a ~~drug.~~ *drug or dosage form.* The bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits to provide coverage for a ~~drug or dose of a drug prescribed by a health care provider~~ *drug, dose of a drug, or dosage form* during utilization review and any ~~appeals.~~ *appeals if that drug has been previously approved for a medical condition of the enrollee or insured and has been prescribed by a health care provider.* The bill would prohibit a

plan or insurer from seeking reimbursement for that coverage if the final utilization review decision is to deny coverage for the prescription ~~drug or dosage.~~ *drug, dose, or dosage form.*

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 or dose of a drug on the basis that the drug or dose of the drug is prescribed for a use or ~~dosage level~~ *dose* that is different from the use or ~~dosage level~~ *dose* for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that 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, the drug is medically necessary to treat that 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) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

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

(c) This section does not apply to coverage for any drug that was denied in a final utilization review pursuant to Section 1367.28.

~~(c)~~

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

~~(d)~~

(e) This section does not prohibit a health care service plan from charging a subscriber or enrollee a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

SEC. 3. Section 1367.28 is added to the Health and Safety Code, to read:

1367.28. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits shall provide coverage for a ~~drug or dose of a drug prescribed by a health care provider~~ *drug, dose of a drug, or dosage form* during the entire duration of utilization review and any appeals of utilization ~~review.~~ *review if that drug has been previously approved for coverage by a health care service plan for a medical condition of the enrollee and has been prescribed by a health care provider.*

(b) A health care service plan shall not seek reimbursement from an enrollee, health care provider, or other person for prescription drug coverage during utilization review if the final utilization review decision is to deny coverage for that prescription ~~drug or dosage.~~ *drug, dose, or dosage form.*

(c) For purposes of this section, "utilization review" means prospectively, retrospectively, or concurrently reviewing and approving, modifying, delaying, or denying, based in whole or in part on medical necessity, a request by a health care provider, enrollee, or authorized representative of a provider or enrollee for coverage of a prescription drug.

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

10123.190. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits shall provide coverage for a ~~drug or dose of a drug prescribed by a health care provider~~ *drug, dose of a drug, or dosage form* during the entire duration of utilization review and any appeals of utilization ~~review.~~ *review if that drug has been previously approved for coverage by a health insurer for a medical condition of the insured and has been prescribed by a health care provider.*

(b) A health insurer shall not seek reimbursement from an insured, health care provider, or other person for prescription drug coverage during utilization review if the final utilization review decision is to deny coverage for that prescription ~~drug or dosage.~~ *drug, dose, or dosage form.*

(c) For purposes of this section, "utilization review" means prospectively, retrospectively, or concurrently reviewing and approving, modifying, delaying, or denying, based in whole or in part on medical necessity, a request by a health care provider, insured, or authorized representative of a provider or insured for coverage of a prescription drug.

SEC. 5. Section 10123.195 of the Insurance Code is amended to read:

10123.195. (a) A group or individual disability insurance policy issued, delivered, or renewed in this state or certificate of group 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, directly or indirectly covers prescription drugs shall not limit or exclude coverage for a drug or dose of a drug on the basis that the drug or dose of the drug is prescribed for a use or ~~dosage level~~ *dose* that is different from the use or ~~dosage level~~ *dose* for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that 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 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) It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of subdivision (a), if requested by the insurer.

(c) 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) 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) 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) 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) This section shall not apply to a policy of disability insurance that covers hospital, medical, or surgical expenses which is issued outside of California to an employer whose principal place of business is 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 investigational, 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.

SEC. 6. 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 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.[27] 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.[28]

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 Under Review Coverage, Off-Label, and Continuity mandates for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to the survey enabled CHBRP to estimate baseline rates of prior authorization requests. The survey also provided the number of approved prior authorizations and appeals, allowing a calculation of the denial rate. Responses to this survey represent 92% of commercial enrollees with health insurance that can be subject to state benefit mandates.

CHBRP's typical data source does not contain information related to utilization review for outpatient prescription drug claims, so the data used for this analysis is 2021 pharmacy claims data from Milliman's MyRxConsultant.

Analysis-Specific Caveats and Assumptions

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

- SB 853 would affect the utilization of drugs — predominantly maintenance drugs — which CHBRP identified using the Medi-Span® Maintenance Indicator. Maintenance drugs are typically for self-administered therapy, with low probability for dosage changes, and for which the drug's most common use is to treat chronic disease.
- CHBRP calculated the average unit cost per 30-day supply of a drug. Milliman's MyRxConsultant data contains a mix of 30-day and 90-day supplies; CHBRP adjusted the unit costs to ensure each script filled was a 30-day supply. While many enrollees obtain 90-day supplies for drugs covered under their prior plan or policy, SB 853 only requires coverage during the period of review or appeal. Therefore, it would not be reasonable to assume a 90-day supply would be dispensed postmandate.
- Baseline utilization was based on plan/insurer survey responses, which indicated the number of prior authorization request reviews and appeals in total, as well as MyRxConsultant, which indicated the number of scripts filled for drugs with prior authorization requirements. As discussed above, baseline utilization was adjusted to account for plan/insurer appeals and regulator appeals.
    - Considering the possibility of appeals to plans/insurers and to regulators, CHBRP made an adjustment to total baseline utilization, increasing total baseline utilization by 11%.

[27] 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.
[28] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2022 Cost Analyses: Data Sources, Caveats, and Assumptions*.

  - Plan/insurer survey responses indicated that 30% of all prior authorization requests result in a denial.
  - CHBRP assumed that the denial rate for all prior authorizations was identical to the denial rate for appeals.
  - At baseline, CHBRP assumed that 80% of denials for prior authorizations result in utilization of an alternative drug.[29]
- The following assumptions were made about enrollee behavior:
  - CHBRP has assumed that 20% of enrollees won't fill a script for an approved prior authorization at baseline or won't fill a script when newly covered under SB 853. Postmandate, CHBRP has assumed 10% of enrollees who did not fill a script with an approved authorization or appeal at baseline would obtain coverage for the script (Fischer et al., 2011).
  - Maintenance drugs with utilization review requirements are anticipated to be the predominant type of drug impacted,[30] as the three mandates related to drugs to treat a specified condition or changes in dose or dosage form (which would occur predominantly for a maintenance drug with an ongoing prescription). Maintenance drugs with utilization review requirements were the drugs modeled during the analysis.
    - While there may be instances where changes in dosage form or dosage strength for non-maintenance drugs, CHBRP expects these occurrences to be rare.
    - CHBRP assumed that 77% of prior authorizations would be for maintenance drugs and may result in up to a 12-month supply, based on Milliman's MyRxConsultant.
- CHBRP used industry data to develop assumptions for population churn — that is, the percentage of enrollees who change plans/policies during the year and are therefore likely to use the Under Review Coverage mandate to continue coverage for recurring scripts. CHBRP has used the following annual churn rates by market segment (Covered California, 2018; Graves, 2018; Sommers et al., 2016):
  - Large group: 13.4%
  - Small group: 13.4%
  - Individual: 33.3%
  - CalPERS HMOs: 12.0%
- Because plans would be able to continue using utilization management techniques, CHBRP has not modeled any additional churn arising from SB 853 stemming from changes in enrollee behavior. CHBRP anticipates that enrollees would not be motivated to switch plans given that the new plan may still have prior authorization requirements and formulary requirements.
- Rebates were not modeled as offsetting costs for SB 853.
- CHBRP estimated that the number of scripts written with prior authorization requirements would increase by 0.5%.[31] This assumption captures changes in prescribing patterns and utilization of scripts filled arising from the Under Review Coverage mandate, Off-Label mandate, and Continuity mandate.

[29] Personal communication, J. Watanabe, March 22, 2022.
[30] Personal communication, J. Watanabe, March 18, 2022.
[31] Personal communication, J. Watanabe, March 11, 2022.

Table 5 provides the top 10 drugs with utilization review requirements by the number of scripts filled using 2021 pharmacy claims experience.

Table 5. Most Common Drugs with Utilization Review Requirements, 2021

	Drug Name
1	AMPHETAMINE/DEXTROAMPHETAMINE
2	VYVANSE
3	HUMIRA PEN
4	METHYLPHENIDATE HCl
5	SAXENDA
6	EMGALITY
7	TESTOSTERONE CYPIONATE
8	TRULICITY
9	AIMOVIG
10	DUPIXENT

Source: California Health Benefits Review Program, 2022.

- As a simplifying assumption, CHBRP did not explicitly model those enrollees receiving the ultimately approved drug several days earlier than they would in the absence of the mandate. CHBRP did assume an overall increase in utilization, which would implicitly address any increase stemming from an earlier script filled.

- To estimate unit cost of scripts filled for alternative drugs (those with less stringent prior authorization requirements), CHBRP used the MyRxConsultant database to calculate the average unit cost of drugs requiring prior authorization by tier. CHBRP then projected the assumed change in drug tier for alternative drug script fills. For each tier, CHBRP assumed that 25% of the alternative drug script fills would be for the same tier, and 75% for one tier lower. So, for example, a script for a denied brand-specialty drug would alternatively be filled with either another brand-specialty drug or brand drug, with a probability of 25% and 75% respectively. CHBRP's assumptions are shown in Table 6.

Table 6. Assumptions for Determining Cost of Alternative Drugs

Tier of Drug Denied Prior Authorization	Tier of Alternative Drug				Average Unit Cost (30-day Supply)
	Brand-Specialty	Generic-Specialty	Brand	Generic	
Brand-Specialty	25%		75%		$5,985
Generic-Specialty		25%	75%		$4,280
Brand			25%	75%	$561
Generic				100%	$50

Source: California Health Benefits Review Program, 2022.

- The net impact of the assumptions above is a shift in utilization by drug tier that puts more utilization on drugs with lower unit costs, as shown in Table 7:

Table 7. Assumptions for Determining Cost of Alternative Drugs (Cont'd)

Drug Tier	% of Approved Scripts Filled	% of Alternative Scripts Filled	Average Unit Cost (30-day Supply) – Approved Scripts Filled	Average Unit Cost (30-day Supply) – Alternative Scripts Filled
Brand-Specialty	24%	6%	$5,985	$5,985
Generic-Specialty	1%	0%	$4,280	$4,280
Brand	37%	27%	$561	$561
Generic	39%	66%	$50	$50
All Alternative Scripts Filled	**100%**	**100%**	**$1,670**	**$548**

Source: California Health Benefits Review Program, 2022.

- Utilization per enrollee and unit costs were trended from 2021 to 2023 using trends of 1.8% and (-0.8%), respectively.
- As described in the *Benefit Coverage, Utilization, and Cost Impacts* section, SB 853 would increase scripts filled for drugs where a prior authorization is ultimately approved or denied, while decreasing scripts filled for alternative drugs. This shift in utilization towards drugs with higher unit

costs ultimately increases the average cost per script filled postmandate. Table 8 provides more detail on the numbers presented in Table 1.

Table 8. Detail on Impacted Scripts Filled

	Baseline (2023)	Postmandate Year 1 (2023)	Increase/ Decrease	Change Postmandate
Impacted Scripts Filled				
Drugs with review ultimately approved	778,923	798,396	19,473	2.50%
Drugs with review ultimately denied	-	25,366	25,366	0.00%
Drugs that are filled as an alternative to drugs denied after utilization review	329,827	307,838	(21,988)	-6.67%
Total impacted scripts filled	1,108,750	1,131,601	22,851	2.06%
Average Cost per Script Filled				
Drugs with review ultimately approved	$1,670	$1,674	$4	0.24%
Drugs with review ultimately denied		$1,837	$1,837	0.00%
Drugs that are filled as an alternative to drugs denied after utilization review	$548	$548	$0	0.00%
Average cost per script filled — all impacted scripts filled	$1,336	$1,372	$36	2.67%

Source: California Health Benefits Review Program, 2022.

APPENDIX C UTILZATION MANAGEMENT TECHNIQUES

This section provides an overview of the utilization management techniques used for health insurance benefits, including coverage of prescription drugs through a pharmacy benefit.

Utilization management techniques are used by health plans and insurers to control costs, ensure drug compatibility, and manage safety. Examples include benefit coverage requirements related to prior authorization, step therapy, quantity limits, and limits related to the age or sex of the enrollee (such as prescription-only infant formula or prostate cancer screening for men). A brief description of some key utilization management techniques follows.

Prior authorization

Prior authorization — also known as precertification, prior approval, or prospective review — is a utilization management technique commonly used by health insurance plans and insurers to ensure that a given medical intervention meets the insurance plan or policy's criteria for coverage (Newcomer et al., 2017). Prior authorization was developed as a tool for insurers to assess the appropriateness of treatment that would result in a hospital admission or a high-cost procedure (Resneck, 2020). The process typically requires prescribers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before either medical services are provided or a prescription is filled in order to qualify for payment.

Step Therapy

Step therapy or "fail-first" protocols may be applied to prescription drugs by health plans and insurers to control costs, ensure drug compatibility, and manage safety. Health plans/insurers may use step therapy protocols to apply clinical guidelines established by professional societies and other recognized organizations to treatment plans. They require an enrollee to try and fail one or more drugs prior to receiving coverage for the drug with step therapy requirements. Step therapy protocols usually recommend starting with a drug that is less expensive (generics) and/or has more "post-marketing safety experience" (PBMI, 2015). In addition, they sometimes require starting with a less potent drug or dosage, perhaps with fewer side effects, and graduating to more potent drugs as necessary (e.g., from prescription Motrin to OxyContin to treat pain). Generally, more expensive or more potent drugs are covered when the patient fails to respond to the step therapy–required drug (PBMI, 2018).

Formulary

A formulary is a list of covered prescription drugs. Coverage is based on evaluations of efficacy, safety, and cost-effectiveness of drugs. Health plans and insurers develop formularies and cover the drugs listed on them. In general, outpatient prescription drug formularies can be characterized by the number of tiers into which the drugs are divided, each tier having a distinct cost-sharing level. The prescription drugs in the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some health plans or insurers use a four-tier (or higher) system that generally includes lifestyle drugs (e.g., infertility, erectile dysfunction, weight loss) and specialty drugs (i.e., biological agents treating rheumatoid arthritis or multiple sclerosis); typically, these are the most expensive drugs. Regardless of the tier structure, California law generally limits the enrollee cost of a 30-day supply per prescription to $250.[32]

[32] H&SC 1342.73; IC 10123.1932. 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 a plan with a deductible.

REFERENCES

Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee. Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy. *Journal of Managed Care & Specialty Pharmacy.* 2019;25(6):641-644.

Afendulis CC, He Y, Zaslavsky AM, Chernew ME. The impact of Medicare Part D on hospitalization rates. *Health Services Research*. 2011;46(4):1022-1038.

Allen SN, Ojong-Salako M. Pharmacist-initiated prior authorization process to improve patient care in a psychiatric acute care hospital. *Journal of Pharmacy Practice.* 2015;28(1):31-34.

California Health Benefits Review Program (CHBRP). *Abbreviated Analysis of California Assembly Bill 933 Prescription Drug Cost Sharing*. 2022. Berkeley, CA.

Centers for Medicare and Medicaid Services (CMS). Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements (Rev 18, 01-15-16). 2016. Available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf. Accessed March 6, 2022.

Centers for Medicare and Medicaid Services (CMS). Notice of Benefit and Payment Parameters for 2022 Final Rule Part Two Fact Sheet. 2021. Available at: https://www.cms.gov/newsroom/fact-sheets/notice-benefit-and-payment-parameters-2022-final-rule-part-two-fact-sheet. Accessed November 15, 2021.

Covered California. *Coverage When You Need It: Lessons from Insurance Coverage Transitions in California's Individual Marketplace Pre and Post the COVID-19 Pandemic*. Covered California Policy Brief; September 22, 2020. Available at: https://hbex.coveredca.com/data-research/library/CoveredCA_Coverage-When-You-Need-It_09-22-20.pdf. Accessed March 6, 2022.

Fischer MA, Choudhry NK, Brill G, et al. Trouble getting started: predictors of primary medication nonadherence. *American Journal of Medicine*. 2011;124(11):1081.

Graves, John A. *Coverage Churn in California*. Presentation to California Select Committee on Health Delivery Systems and Universal Coverage, January 2018. Available at: https://healthcare.assembly.ca.gov/sites/healthcare.assembly.ca.gov/files/graves-USE%20THIS-general-assembly.pdf. Accessed March 6, 2022.

Johnson & Johnson Interactive Tool. Available at https://www.janssencarepath.com/sites/www.janssencarepath-v1.com/files/know-your-state.pdf. Accessed on March 13, 2022.

Jones LK, Ladd IG, Gionfriddo MR, Gregor C, Evans MA, Graham J. Medications requiring prior authorization across health insurance plans*. American Journal of Health-System Pharmacy*. 2020;77(8):644-648.

Newcomer LN, Weininger R, Carlson RW. Transforming Prior Authorization to Decision Support. *Journal of Oncology Practice.* 2017;13(1):e57-e61.

National Council on Aging (NCOA). Medicare Part D Transition Policy. 2020. Available at: https://www.ncoa.org/article/medicare-part-d-transition-policy. Accessed March 6, 2022.

Pharmacy Benefits Management Institute (PBMI). 2014-2015 Prescription Drug Benefit Cost and Plan Design Report. Plano, TX: PBMI; 2015.

Pharmacy Benefits Management Institute (PBMI). 2018 Trends in Specialty Drug Benefits Report. Plano, TX: PBMI; 2018.

Resneck JS. Refocusing Medication Prior Authorization on Its Intended Purpose. *JAMA.* 2020;323(8):703-704.

Sommers BD, Gourevitch R, Maylone B, Blendon RJ, Epstein AM. Insurance Churning Rates For Low-Income Adults Under Health Reform: Lower Than Expected But Still Harmful For Many. *Health Affairs (Millwood).* 2016 1;35(10):1816-1824.

Sullivan SD, Yeung K, Vogeler C, et al. Design, implementation, and first-year outcomes of a value-based drug formulary. *Journal of Managed Care & Specialty Pharmacy*. 2015;21(4):269-75.

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.

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Adara Citron, MPH, Principal Policy Analyst
Sabrina Woll, Policy Associate
Karen Shore, **PhD,** Contractor*
An-Chi Tsou, PhD, Contractor*
*Independent Contractor working with CHBRP to support analyses and other projects.

Faculty Task Force

Paul Brown, PhD, University of California, Merced
Timothy T. Brown, PhD, University of California, Berkeley
Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness,* University of California, San Francisco
Todd Gilmer, PhD, University of California, San Diego
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Elizabeth Magnan, MD, PhD, *Co-Vice Chair for Public Health*, University of California, Davis
Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego
Joy Melnikow, MD, MPH, *Co-Vice Chair for Public Health*, University of California, Davis
Aimee Moulin, MD, University of California, Davis
Jack Needleman, PhD, University of California, Los Angeles
Mark A. Peterson, PhD, University of California, Los Angeles
Nadereh Pourat, PhD, *Vice Chair for Cost*, University of California, Los Angeles
Dylan Roby, PhD, University of California, Irvine
Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Bethney Bonilla, MA, University of California, Davis
Danielle Casteel, MA, University of California, San Diego
Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton
Margaret Fix, MPH, University of California, San Francisco
Naomi Hillery, MPH, University of California, San Diego
Jeffrey Hoch, PhD, University of California, Davis
Julia Huerta, MPH, University of California, Davis
Michelle Keller, PhD, MPH, University of California, Los Angeles
Jacqueline Miller, University of California, San Francisco
Marykate Miller, MS, University of California, Davis
Amy Quan, University of California, San Francisco
Dominique Ritley, MPH, University of California, Davis
Emily Shen, University of California, Los Angeles
Riti Shimkhada, PhD, University of California, Los Angeles
Meghan Soulsby Weyrich, MPH, University of California, Davis
Steven Tally, PhD, University of California, San Diego
Sara Yoeun, MPH, University of California, San Diego

National Advisory Council

Lauren LeRoy, PhD, Strategic Advisor, L. LeRoy Strategies, Chair
Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Allen D. Feezor, Former Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC
Charles "Chip" Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President Emeritus, ECRI Institute Headquarters, Plymouth Meeting, PA; Adjunct Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania
Donald E. Metz, Executive Editor, *Health Affairs,* Bethesda, MD
Dolores Mitchell, (Retired) Executive Director, Group Insurance Commission, Boston, MA
Marilyn Moon, PhD, Senior Fellow, Retired, American Institutes for Research, Washington, DC
Carolyn Pare, (Retired) President and CEO, Minnesota Health Action Group, Bloomington, MN
Richard Roberts, MD, JD, Professor Emeritus of Family Medicine, University of Wisconsin-Madison, Madison, WI
Alan Weil, JD, MPP, Editor-in-Chief, *Health Affairs,* Bethesda, MD

ACKNOWLEDGMENTS

CHBRP gratefully acknowledges the efforts of the team contributing to this analysis:

John Rogers, ASA, MAAA, and Katherine DeSimone, ASA, MAAA, provided the cost and actuarial analysis. Jonathan H. Watanabe, PharmD, PhD, of the University of California, Irvine, provided technical assistance with the literature search and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see previous page of this report) and members of the CHBRP Faculty Task Force, Jack Needleman, PhD, of the University of California, Los Angeles, and Marilyn Stebbins, PharmD, of the University of California, San Francisco, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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.

Garen Corbett, MS
Director

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