CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Abbreviated Analysis

California Assembly Bill 1060: Naloxone Hydrochloride, as Amended June 12, 2023

Prepared by
California Health Benefits Review Program
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Report to the 2023–2024
California State Legislature
June 23, 2023

SUMMARY

The California Senate Committee on Health requested that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of California Assembly Bill (AB) 1060, as amended on June 12, 2023. AB 1060 as amended would require coverage of prescription and nonprescription naloxone hydrochloride (naloxone), if the medication is approved by the U.S. Food and Drug Administration (FDA), for treatment of an opioid overdose. AB 1060 would also prohibit cost sharing, including application of a deductible or copayment, exceeding $10 for prescription or nonprescription naloxone.

The FDA formally authorized Narcan, a brand-name prescription naloxone nasal spray, to be sold without a prescription in late March 2023. It is expected that Narcan will be available in stores later in 2023.

This analysis builds off of CHBRP's analysis of AB 1060 as introduced. Additional information about policy context and background are included in the Abbreviated Analysis published on April 19, 2023.[1]

Context

Opioid use disorder prevalence in California was 1.58% among people aged 12 years and older in 2021.

In 2021, 7,175 Californians died from an opioid-related overdose, which was in increase of 119% from 2019. About 21,000 Californians were seen in emergency departments for opioid-related overdose in 2021 and over 5,000 Californians were hospitalized for opioid-related overdose.

Naloxone is an opioid antagonist, meaning that it binds to opioid receptors throughout the body, thus reversing and blocking the effects of opioids. Naloxone can be used for all opioids, including natural compound opiates (such as morphine, heroin, and/or codeine), semi-synthetic opioids (such as hydrocodone, oxycodone, and/or hydromorphone), and synthetic opioids (such as fentanyl, carfentanil, and/or tramadol).

Relevant Population

If enacted, AB 1060 as amended would apply to the health insurance of 24,853,000 California enrollees (64% of all Californians). This represents those who have commercial or CalPERS health insurance regulated by DMHC and CDI and Medi-Cal beneficiaries enrolled in DMHC-regulated plans or county organized health systems (COHS).

Benefit Coverage

Implementation of AB 1060 as amended would be staggered. In Year 1 (2024), plans and policies in the large group market, CalPERS, and Medi-Cal would be required to implement the bill. In Year 2 (2025), plans and policies in the individual and small group markets would be required to comply. Postmandate, 100% of enrollees would have coverage fully compliant with AB 1060 as amended, meaning prescription and nonprescription naloxone would be covered with cost sharing not exceeding $10 per package of naloxone.

Utilization and Expenditures

Because there are no estimates available as to the utilization rate of nonprescription naloxone, as an illustrative example, CHBRP assumed 20% of enrollees with an opioid addiction would receive one kit of nonprescription naloxone postmandate and 5% of commercial and Medi-Cal enrollees with an opioid addiction would have one family member who would also receive one kit of nonprescription naloxone.

In Year 1, CHBRP estimates that use of prescription naloxone (nasal sprays and

[1] CHBRP's first analysis of AB 1060 is available at: https://www.chbrp.org/analysis/completed-analyses

injections) would not increase. Average cost sharing at baseline for prescription naloxone for enrollees in the large group market, CalPERS, and Medi-Cal is below the $10 cost sharing limit, and therefore there would be no induced utilization as a result of lower cost sharing due to AB 1060. Use of nonprescription naloxone (nasal sprays) covered by insurers will increase from 16,361 to 77,420 due to the coverage of nonprescription naloxone. The increased utilization is driven both by the proposed legislation's reduction of cost sharing as well as by removal of the need for a prescription.

In Year 2, when the small group and individual markets would be required to implement AB 1060 as amended, utilization of prescription and nonprescription naloxone would increase. An additional 12,510 enrollees would obtain prescription naloxone, while an additional 11,520 enrollees would obtain nonprescription naloxone.

In the illustrative example, AB 1060 as amended would increase total net annual expenditures by $3,467,000 or 0.002% (Figure A) in Year 1 and $3,732,000 in Year 2 (Figure B). AB 1060 would increase premiums by about $4.1 million in Year 1 and $4.8 million in Year 2.

There are two types of cost sharing impacts for enrollees: the first is a reduction in cost sharing for prescription naloxone, and the second is a reduction in expenses for previously noncovered nonprescription naloxone. In Year 1, enrollees would experience an increase in cost sharing for covered benefits of $202,000 due to both new utilization and a shift of expenses from the noncovered category to the covered category. Expenses for noncovered benefits would decrease by $818,000. In Year 2, cost sharing for covered benefits would increase by $336,000 and expenses for noncovered benefits would decrease by $1,386,000.

Figure A. Expenditure Impacts of AB 1060 as Amended, Year 1

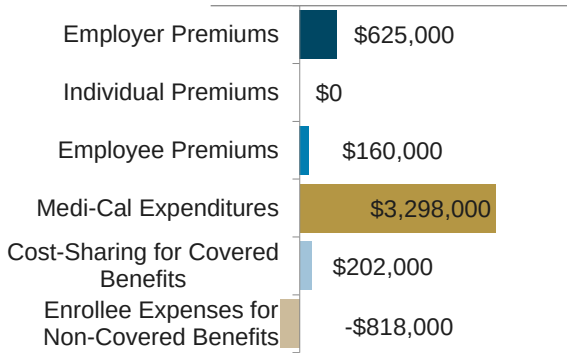
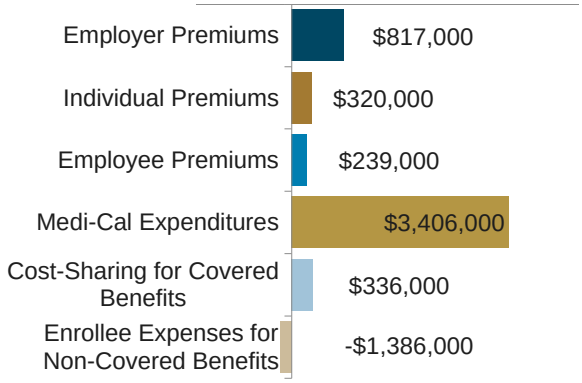


Figure B. Expenditure Impacts of AB 1060 as Amended, Year 2



POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[2] conduct an evidence-based assessment of the financial impacts of Assembly Bill (AB) 1060, Naloxone Hydrochloride, as amended on June 12, 2023. This analysis builds off of CHBRP's analysis of AB 1060 as introduced. Additional information about policy context, background, and public health impacts are included in the Abbreviated Analysis published on April 19, 2023.[3]

Bill-Specific Analysis of AB 1060, Naloxone Hydrochloride, as Amended June 12, 2023

Amended Bill Language

AB 1060 as amended would:

- Require coverage of prescription and nonprescription naloxone hydrochloride (naloxone) or another drug approved by the United States Food and Drug Administration (FDA) for complete or partial reversal of an opioid overdose;
- Limit cost sharing, including application of a deductible or copayment, for prescription or nonprescription naloxone or another drug to $10 per package;
- Stagger implementation of the bill (individual and small group market plans and policies would be required to comply as of January 1, 2025, while other markets would be required to comply January 1, 2024); and
- Provide language regarding high deductible health plans (see below).

The text of AB 1060 as amended can be found in Appendix A.

High Deductible Health Plans

AB 1060 as amended states "If a health care service plan contract [or policy] is a 'high deductible health plan' under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, the contract shall not impose cost sharing as specified in this section, unless not applying cost sharing would conflict with federal requirements for high deductible health plans."

The Internal Revenue Service has established a set of benefits that are eligible for "first-dollar coverage" (i.e. coverage for services without an enrollee being required to meet their deductible), however, naloxone is not on that list of services. Therefore, requiring high deductible health plans (HDHPs) as defined to comply with AB 1060 could place their status at risk. The above quoted language attempts to ensure HDHPs are able to maintain this federal designation.

However, the language as included in AB 1060 is murky as drafted. There are two potential layperson interpretations of this language.

1. This cost-sharing limit would only apply to HDHPs once an enrollee meets their deductible.

[2] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[3] CHBRP's first analysis of AB 1060 is available at: https://www.chbrp.org/analysis/completed-analyses

2. HDHPs are not required to comply with AB 1060 unless not doing so would conflict with federal requirements for HDHPs, thereby exempting the coverage of enrollees in HDHPs from complying with AB 1060.

After discussions with Committee staff, CHBRP will interpret this language in accordance with scenario 1.

California Regulating Agencies

DMHC: California Department of Managed Health Care
CDI: California Department of Insurance
DHCS: Department of Health Care Services, which administers Medi-Cal

Relevant Populations

If enacted, AB 1060 as amended would apply to the health insurance of 24,853,000 California enrollees (64% of all Californians) (see Table 1). This represents those who have commercial or CalPERS health insurance regulated by DMHC and CDI and Medi-Cal beneficiaries enrolled in DMHC-regulated plans or county organized health systems (COHS).

Table 1. Californians with State-Regulated Health Insurance Subject to AB 1060, 2024

Type of Health Insurance	# of Enrollees in CA
Commercial plans regulated by DMHC and policies regulated by CDI	13,143,000
CalPERS plans regulated by DMHC	882,000
DMHC-regulated Medi-Cal managed care plans	8,817,000
Medi-Cal county organized health systems	2,010,000

Source: California Health Benefits Review Program, 2023.

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

Enrollment in Health Savings Account-Qualified HDHPs

In 2024, CHBRP estimates 7% of commercial and CalPERS enrollees will be enrolled in HSA-qualified HDHPs.[4]

Interaction With Existing State and Federal Requirements

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

Federal Policy Landscape

U.S. Food and Drug Administration (FDA)

The FDA formally authorized Narcan, a brand-name prescription naloxone nasal spray, to be sold without a prescription in late March 2023 (FDA, 2023; Hoffman, 2023). It is expected that Narcan will be available in stores later in 2023. The initial over-the-counter approval was limited to the branded formulation produced by Emergent BioSolutions, but similar generic naloxone nasal sprays will likely be available in the near future. Other forms of naloxone, such as injectable, will still require a prescription.

[4] More information about enrollment in HDHPs is available in CHBRP's resource *Deductibles in State-Regulated Health Insurance*, available at https://www.chbrp.org/other-publications/resources.

Manufacturer Announcement of Pricing

In April 2023, Emergent BioSoluations, the manufacturer of Narcan, announced it plans to price Narcan at less than $50 for two doses (Emergent, 2023).

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, including the requirement for certain health insurance to cover essential health benefits (EHBs).[5,6] In California, nongrandfathered[7] individual and small-group health insurance is generally required to cover EHBs.[8] In 2024, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs. [9]

Because prescription drugs are an EHB category, the portion of AB 1060 that requires coverage of prescription naloxone without cost sharing would not require coverage for a new state benefit mandate and therefore does not exceed the definition of EHBs in California. It is unclear whether the requirement to provide coverage of nonprescription naloxone without cost sharing would exceed EHBs.[10] Although medically necessary treatment for substance use disorder within applicable clinical guidelines is within the EHB standard, as is emergency care, the circumstances under which nonprescription naloxone may be obtained may not fall within these categories.

[5] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[6] 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.
[7] 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.
[8] 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.
[9] See CHBRP's resource *Sources of Health Insurance in California for 2024* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, both available at https://chbrp.org/other_publications/index.php.
[10] Personal communication with DMHC, March 28, 2023.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 1060 as amended would require coverage of prescription and nonprescription naloxone hydrochloride (naloxone), with cost sharing not to exceed $10 per package. AB 1060 applies to enrollees in health plans and health policies regulated by DMHC[11] or CDI as well as to beneficiaries in Medi-Cal.

This section presents an illustrative example of potential incremental impacts of AB 1060 as amended on estimated baseline benefit coverage, utilization, and overall cost. It is challenging to estimate naloxone administration in the United States because of the various trained and untrained people who potentially administer it (Quinn et al., 2023). Additionally, naloxone is frequently administered outside of the medical system.

Analytic Approach and Key Assumptions

CHBRP's approach is largely similar to the approach taken in the first analysis of AB 1060, with a few modifications due to the amended language.

CHBRP assumed all naloxone baseline and postmandate utilization would be processed through the outpatient pharmacy benefit.

When utilization rates are mentioned in this section, it indicates a person filled a prescription or received nonprescription naloxone from a pharmacy. This section does not comment on the administration of the naloxone in the event of an overdose. CHBRP assumed the prescription utilization rate for enrollees with coverage postmandate would increase due to induced utilization caused by the removal of cost sharing. The induced utilization factors were developed using the 2023 Milliman Health Cost Guidelines. Because Medi-Cal plans do not have cost sharing, the prescription utilization rate for Medi-Cal enrollees remains unchanged postmandate.

The Substance Abuse and Mental Health Services Administration (SAMHSA) reports 1.58% of Californians aged 12 and over have an opioid addiction (SAMHSA, 2023). Because there are no estimates available as to the utilization rate of nonprescription naloxone, CHBRP performed an analysis as an illustrative example. For the illustrative example, CHBRP assumed 20% of enrollees with an opioid addiction would receive one kit of nonprescription naloxone postmandate and 5% of commercial and Medi-Cal enrollees with an opioid addiction would have one family member who would also receive one kit of nonprescription naloxone. CHBRP assumed all nonprescription utilization for naloxone would be nasal spray.[12]

CHBRP assumed the average cost per script would not change as a result of AB 1060.

Due to amended bill language and new publicly available information:

- CHBRP assumes cost sharing for nonprescription naloxone would be $10 for enrollees in commercial and CalPERS plans or policies. Medi-Cal beneficiaries would have $0 cost sharing.
    - Enrollees in health savings account (HSA)-qualified high deductible health plans (HDHPs) would be required to meet their plan or policy deductible before cost sharing would be limited to $10. As a simplifying assumption, CHBRP has assumed the

[11] This includes approximately 73% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS).
[12] See the *Policy Context* for information about the FDA's discussion of which naloxone products were approved for nonprescription distribution.

deductible threshold for all enrollees in these plans is $1,600, which is the federal deductible threshold for plans or policies to be designated an HDHP in 2024.

- CHBRP assumes the unit cost of nonprescription naloxone would be $50, in accordance with the announcement from the manufacturer of Narcan. The unit cost of prescription naloxone was obtained through claims data.

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

Baseline and Postmandate Benefit Coverage

At baseline, CHBRP assumes all enrollees have access to prescription and nonprescription naloxone, although only prescription would be covered by their plan or policy. Cost sharing for prescription naloxone at baseline would be subject to an enrollee's prescription drug coverage benefit design.

As mentioned in the *Policy Context* section, implementation of AB 1060 as amended would be staggered. In Year 1 (2024), plans and policies in the large group market, CalPERS, and Medi-Cal would be required to implement the bill. In Year 2 (2025), plans and policies in the individual and small group markets would be required to comply. Postmandate, 100% of enrollees would have coverage fully compliant with AB 1060 as amended.

Almost all — 95.6% — commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications.[13] Among commercial/CalPERS enrollees, 1.2% do not have a pharmacy benefit and 3.2% have a pharmacy benefit that is not regulated by DMHC or CDI. Because AB 1060 does not require creation of a pharmacy benefit — only compliant benefit coverage when a pharmacy benefit is present —baseline benefit coverage for enrollees without a pharmacy benefit or whose pharmacy benefit is not regulated by DMHC or CDI is compliant.

Baseline and Postmandate Utilization

In Year 1, CHBRP estimates that use of prescription naloxone (nasal sprays and injections) would not increase. Average cost sharing at baseline for prescription naloxone for enrollees in the large group market, CalPERS, and Medi-Cal is below the $10 cost sharing limit, and therefore there would be no induced utilization as a result of lower cost sharing due to AB 1060. Use of nonprescription naloxone (nasal sprays) covered by insurers will increase from 16,361 to 77,420 due to the coverage of nonprescription naloxone (Table 2). The increased utilization is driven both by the proposed legislation's reduction of cost sharing as well as by removal of the need for a prescription.

In Year 2, when the small group and individual markets would be required to implement AB 1060 as amended, utilization of prescription and nonprescription naloxone would increase. An additional 12,510 enrollees would obtain prescription naloxone, while an additional 11,520 enrollees would obtain nonprescription naloxone.

Baseline and Postmandate Per-Unit Cost

The average cost per prescription for prescription naloxone (nasal sprays and injections) would increase by $2 from $47 to $49 postmandate. The $2 cost increase is because of changes in enrollee mix; the actual cost of the prescriptions do not change. More commercial enrollees will obtain prescription

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

naloxone when cost sharing is lowered (i.e., cost sharing = $10), but the quantity of Medi-Cal enrollees remains the same. Since the Medi-Cal cost per prescription is cheaper, the overall average cost per prescription increases modestly as the weighted average now tilts in favor of the more expensive cost per prescription values.

The postmandate cost per nonprescription naloxone (nasal sprays) would be $50. It is possible Medi-Cal RX would pay less for naloxone, but CHBRP has assumed the unit cost would be the same across markets.

Baseline and Postmandate Expenditures

In the illustrative example, AB 1060 as amended would increase total net annual expenditures by $3,467,000 or 0.002% in Year 1 and $3,732,000 in Year 2 (see Table 2).

Premiums

Changes in premiums as a result of AB 1060 as amended would vary by market segment. Note that such changes are related to the number of enrollees with health insurance that would be subject to AB 1060.

In the illustrative example, it is estimated that AB 1060 would increase premiums by about $4.1 million in Year 1 and $4.8 million in Year 2. The distribution of the impact on premiums is as follows:

- Year 1 increases:
  - Total premiums for commercial employers purchasing large group health insurance would increase by $569,000, or 0.001%.
  - Total employer premium expenditures for CalPERS HMOs would increase by $56,000, or 0.001%.
  - State expenditures for Medi-Cal would increase by $3,298,000, or 0.008%.
  - Enrollee contributions toward premiums for group insurance would increase by $160,000, or 0.001%.
- Year 2 increases:
  - Total premiums for commercial employers purchasing small or large group health insurance would increase by $760,000.
  - Total premiums for purchasers of individual market health insurance would increase by $320,000.
  - Enrollee contributions toward premiums for group insurance would increase by $336,000.

Enrollee Expenses

In the illustrative example, there are two types of cost sharing impacts for enrollees: the first is a reduction in cost sharing for prescription naloxone, and the second is a reduction in expenses for previously noncovered nonprescription naloxone. In Year 1, enrollees would experience an increase in cost sharing for covered benefits of $202,000 due to both new utilization and a shift of expenses from the noncovered category to the covered category. Expenses for noncovered benefits would decrease by $818,000. In Year 2, cost sharing for covered benefits would increase by $336,000 and expenses for noncovered benefits would decrease by $1,386,000.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding

proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

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

There is a strong evidence base for naloxone. The proposed legislation could have an impact on other health care services if it produces additional use (e.g., changes in emergency services or other health care). There is greater certainty of increased acquisition by enrollees when there is no prescription required and no cost sharing for naloxone. A precise impact on subsequent health care services is less clear.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

At baseline, some enrollees obtain naloxone from community organizations that obtain naloxone through standing orders (see the *Policy Context* for more information). It is possible that the proposed legislation will shift acquisition of a portion of naloxone from original sources to health insurance coverage due to increased benefit coverage and reduced cost sharing, thereby shifting a portion of the financial responsibility from the State to health insurers.

Table 2. Impacts of AB 1060 on Benefit Coverage, Utilization, and Cost, 2024 and 2025

	Baseline (2024)	Postmandate Year 1 (2024)	Postmandate Year 2 (2025)
Benefit Coverage			
Total enrollees with health insurance subject to state-level benefit mandates (a)	24,982,000	24,982,000	25,086,000
Total enrollees with health insurance subject to AB 1060	19,990,000	19,990,000	25,086,000
Utilization and Cost			
Prescription Naloxone (nasal sprays and injections)			
Scripts	27,170	27,170	39,680
Cost per Script	$47	$47	$49
Average cost-share	$5	$5	$8
Nonprescription Naloxone (nasal sprays)			
Scripts (noncovered benefit at baseline)	16,361	77,420	88,940
Cost per Script	$50	$50	$51
Average cost-share	$50	$3	$4
Expenditures			
Premiums			
Employer-sponsored (b)	$57,647,993,000	$57,648,562,000	$60,465,624,000
CalPERS employer (c)	$6,158,262,000	$6,158,318,000	$6,427,951,000
Medi-Cal (excludes COHS) (d)	$41,832,580,000	$41,835,878,000	$43,345,102,000
Enrollee Premiums (expenditures)			
Enrollees, individually purchased insurance	$21,229,233,000	$21,229,233,000	$22,370,302,000
Outside Covered California	$4,867,955,000	$4,867,955,000	$5,010,742,000
Through Covered California	$16,361,278,000	$16,361,278,000	$17,359,560,000
Enrollees, group insurance (e)	$18,263,775,000	$18,263,935,000	$19,150,404,000
Enrollee out-of-pocket expenses			
Cost-sharing for covered benefits (deductibles, copayments, etc.)	$13,857,141,000	$13,857,343,000	$14,553,796,000
Expenses for noncovered benefits (f) (g)	$818,000	$0	$0
Total Expenditures	$158,989,802,000	$158,993,269,000	$166,313,179,000

Source: California Health Benefits Review Program, 2023.

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

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

(c) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five (22.5%) 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).

(d) Includes estimated medical and pharmacy costs for Medi-Cal beneficiaries enrolled in DMHC-regulated plans, COHS managed plans, and dually eligible Medi-Cal beneficiaries not enrolled in DMHC-regulated plans. CHBRP assumes beneficiaries in COHS managed plans have premiums similar to beneficiaries under age 65 enrolled in DMHC-regulated plans and dually eligible Medi-Cal beneficiaries not in DMHC-regulated plans have premiums similar to beneficiaries aged 65 and over enrolled in DMHC-regulated plans.

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

(f) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

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

APPENDIX A TEXT OF BILL ANALYZED

The California Assembly Committee on Health requested that CHBRP provide an updated analysis of AB 1060 as amended on June 12, 2023.

ASSEMBLY BILL **NO. 1060**

Introduced by Assembly Member Ortega
(Coauthors: Assembly Members ~~Arambula and Haney)~~ *Arambula, Haney, Schiavo, and Zbur)*
~~(Coauthor: Senator~~ *(Coauthors: Senators Dodd, Durazo, and* Wahab)

AMENDED IN SENATE JUNE 12, 2023
AMENDED IN ASSEMBLY MARCH 16, 2023

An act to add *and repeal* Section 1374.198 ~~to~~ *of* the Health and Safety Code, to add *and repeal* Section 10127.22 ~~to~~ *of* the Insurance Code, and to add *and repeal* Section 14132.37 ~~to~~ *of* the Welfare and Institutions Code, relating to opioids.

LEGISLATIVE COUNSEL'S DIGEST

AB 1060, as amended, Ortega. Health care coverage: naloxone hydrochloride.

Existing law sets forth various programs relating to opioid overdose prevention and treatment, including, among others, standing orders for the distribution of an opioid antagonist, a naloxone grant program, and a grant program to reduce fentanyl overdoses and use throughout the state.

Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Under existing law, the pharmacist service of furnishing naloxone hydrochloride is a covered Medi-Cal benefit. The Medi-Cal program also covers certain medications to treat opioid use disorders as part of narcotic treatment program services, or as part of medication-assisted treatment services within the Drug Medi-Cal Treatment Program, as specified.

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.

This bill would make legislative findings relating to ~~developments within~~ the United States Food and Drug Administration (FDA) ~~on potentially~~ approving a certain naloxone hydrochloride nasal spray for nonprescription use.

Under the bill, prescription or nonprescription naloxone hydrochloride *or another drug approved by the FDA for the complete or partial reversal of an opioid overdose* would be a covered benefit under the Medi-Cal ~~program, if that medication is approved, for prescription or nonprescription use, respectively, by the FDA for treatment of an opioid overdose.~~ *program.* The bill would require a health care service plan

contract or health insurance policy, as specified, to include coverage for ~~that same medication~~ *the same medications* under the same conditions. The bill would prohibit a health care service plan contract or health insurance policy from imposing any cost-sharing requirements for that ~~coverage, would prohibit the department from subjecting that coverage to any share-of-cost requirements under the Medi-Cal program, and would require that coverage to include the total cost of that medication.~~ *coverage exceeding $10 per package of medication, and would prohibit a high deductible health plan from imposing cost sharing, as specified. The bill would repeal these provisions on January 1, 2030.*

Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The 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.

DIGEST KEY

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

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BILL TEXT

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

SECTION 1.

The Legislature finds and declares all of the following:

(a) According to the United States Food and Drug Administration (FDA), naloxone hydrochloride is a medicine that can counter overdose effects when administered timely and that can help to reduce opioid overdose deaths.

(b) In November 2022, the FDA issued a Federal Register notice with a preliminary assessment of the safety and effectiveness of certain naloxone hydrochloride drug products for nonprescription use, in order to facilitate the development and approval of those products, including through a potential switch from prescription status to nonprescription status.

(c) In February 2023, an advisory committee to the FDA voted unanimously in favor of making Narcan, a naloxone hydrochloride nasal spray, available over the counter.

(d) ~~The FDA is expected to make a final decision by the end of March 2023 on whether to approve~~ *In March 2023, the FDA approved* Narcan for nonprescription use.

(e) The California Overdose Surveillance Dashboard, administered by the State Department of Public Health, contains the following data applicable to the state for 2021:

(1) Seven thousand one hundred seventy-five deaths were documented as relating to an opioid overdose. Of those deaths, 5,961 were documented as relating to a fentanyl overdose.

(2) Eight hundred forty-six deaths were associated with an opioid-related overdose for persons 24 years of age or younger. Of those deaths, 801 were associated with a fentanyl-related overdose.

(3) Twenty-one thousand sixteen emergency department (ED) visits were documented as relating to an opioid overdose. Of those ED visits, 5,644 were associated with a fentanyl-related overdose.

SEC. 2.

Section 1374.198 is added to the Health and Safety Code, immediately following Section 1374.197, to read:

1374.198.

(a) A health care service plan contract that is issued, amended, delivered, or renewed on or after January 1, 2024, *or a contract offered in the individual or small group market on or after January 1, 2025,* shall

include coverage for prescription or nonprescription naloxone ~~hydrochloride, if that medication is approved, for prescription or nonprescription use, respectively, by the United States Food and Drug Administration for treatment of an opioid overdose. A health care service plan contract shall not impose any cost-sharing requirements, including a copayment or deductible, for coverage provided pursuant to this section and shall cover the total cost of prescription or nonprescription naloxone hydrochloride.~~ *hydrochloride or another drug approved by the United States Food and Drug Administration (FDA) for the complete or partial reversal of an opioid overdose.*

(b) A health care service plan contract shall not impose any cost-sharing requirements, including a copayment or deductible, for coverage provided pursuant to this section exceeding ten dollars ($10) per package of naloxone hydrochloride or another drug approved by the FDA for the complete or partial reversal of an opioid overdose.

(c) If a health care service plan contract is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, the contract shall not impose cost sharing as specified in this section, unless not applying cost sharing would conflict with federal requirements for high deductible health plans.

(d) This section shall remain in effect only until January 1, 2030, and as of that date is repealed.

SEC. 3.

Section 10127.22 is added to the Insurance Code, immediately following Section 10127.20, to read:

10127.22.

(a) A health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2024, *or a policy offered in the individual or small group market on or after January 1, 2025,* shall include coverage for prescription or nonprescription naloxone ~~hydrochloride, if that medication is approved, for prescription or nonprescription use, respectively, by the United States Food and Drug Administration for treatment of an opioid overdose. A health insurer shall not impose any cost-sharing requirements, including a copayment or deductible, for coverage provided pursuant to this section and shall cover the total cost of prescription or nonprescription naloxone hydrochloride.~~ *hydrochloride or another drug approved by the United States Food and Drug Administration (FDA) for the complete or partial reversal of an opioid overdose.*

(b) A health insurer shall not impose any cost-sharing requirements, including a copayment or deductible, for coverage provided pursuant to this section exceeding ten dollars ($10) per package of naloxone hydrochloride or another drug approved by the FDA for the complete or partial reversal of an opioid overdose.

(c) If a health insurance policy is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, the policy shall not impose cost sharing as specified in this section, unless not applying cost sharing would conflict with federal requirements for high deductible health plans.

(d) This section shall remain in effect only until January 1, 2030, and as of that date is repealed.

SEC. 4.

Section 14132.37 is added to the Welfare and Institutions Code, immediately following Section 14132.36, to read:

14132.37.

(a) Prescription or nonprescription naloxone hydrochloride *or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of an opioid overdose* shall be a covered benefit under the Medi-Cal ~~program, if that medication is approved, for prescription or nonprescription use, respectively, by the United States Food and Drug Administration for treatment of an opioid overdose. The department shall not subject coverage provided pursuant to this section to any share-of-cost requirements and shall cover the total cost of prescription or nonprescription naloxone hydrochloride.~~ *program.*

(b) This section shall remain in effect only until January 1, 2030, and as of that date is repealed.

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.[14] 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.[15]

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

Analysis-Specific Data Sources

CHBRP assumed all naloxone hydrochloride (naloxone) utilization, both baseline and postmandate, would be processed through the outpatient pharmacy benefit. CHBRP did not consider naloxone utilization processed through the medical benefit. CHBRP included enrollees with DMHC- or CDI-regulated pharmacy benefits or Medi-Cal RX in this analysis.

CHBRP assumed the non–DMHC-regulated, dually eligible Medi-Cal members (Duals) have premiums and coverage similar to the 65 and over members in DMHC-regulated managed Medi-Cal plans, and non–DMHC-regulated county organized health system (COHS) plan members have premiums and coverage similar to the under 65 members in DMHC-regulated managed Medi-Cal plans.

When utilization rates are mentioned in this section, it indicates a person filled a prescription or received nonprescription naloxone from a pharmacy. This section does not comment on the administration of the naloxone in the event of an overdose.

Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

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

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated coverage includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act as well as Medi-Cal RX.
- CHBRP assumed only large group DMHC-regulated commercial insurance plans, large group CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act as well as Medi-Cal RX would be subject to AB 1060 in 2024. CHBRP assumed DMHC and CDI regulated small group and individual policies would be subject to AB 1060 in 2025.
- CHBRP assumed all individuals have baseline coverage for prescription naloxone and all individuals have no baseline coverage for nonprescription naloxone.

[14] 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.
[15] See method documents posted at https://www.chbrp.org/about/analysis-methodology/cost-impact-analysis; in particular, see *2022 Cost Analyses: Data Sources, Caveats, and Assumptions*.

Methodology and Assumptions for Baseline Utilization

- Prescription naloxone nasal spray and injection utilization rates for California commercial and Medi-Cal enrollees were calculated using Milliman's proprietary 2021 Consolidated Health Cost Guidelines™ Sources Database (CHSD).
- The commercial utilization rates were trended from 2021 to 2024 and 2025 using a 1.6% annual trend based on trends from the 2023 Milliman Health Cost Guidelines and the Medi-Cal utilization rates were trended from 2021 to 2024 and 2025 using a 1.0% annual trend.
- The Substance Abuse and Mental health Services Administration reports 1.58% of Californians aged 12 and over have an opioid addition. (From AB1288, SAMHSA, 2023) CHBRP assumed 36% of those Californians were in commercial plans and 38% were in Medi-Cal plans. (From KFF 2019, https://www.kff.org/uninsured/issue-brief/key-facts-about-uninsured-adults-with-opioid-use-disorder/) CHBRP's initial analysis assumed 20% of commercial enrollees with an opioid addiction and 5% of enrollees with an opioid addiction would have a family member who would receive one kit of nonprescription naloxone hydrochloride, if the copayment is $0. Fewer enrollees will receive nonprescription naloxone hydrocholoride if they must pay the full cost. Using the Health Cost Guidelines, CHBRP applied induced utilization adjustment factors to determine the percentage of enrollees who would receive naloxone hydrochloride if they had to pay the full price of the drug.
- Commercial utilization was split between HSA and non-HSA plans based on the average enrollee cost sharing and utilization adjustment factors.
- CHBRP assumed Medi-Cal enrollees would not purchase nonprescription naloxone at baseline.

Methodology and Assumptions for Baseline Cost

- CHBRP calculated the California average commercial cost per script of naloxone using 2021 CHSD.
- The average commercial cost per script was trended from 2021 to 2024 and 2025 using a 2.9% annual trend.
- The 2024 and 2025 commercial average cost per script was discounted 73% to estimate the Medicaid average cost per script, based on contracting/reimbursement differentials (McBeth et al., 2021; Zuckerman et al., 2021).
- The 2024 assumed cost of naloxone hydrochloride nasal spray for the commercial population is $50, based on a manufacturer pricing announcement.(https://www.emergentbiosolutions.com/media-statement/emergents-statement-on-over-the-counter-access-availability-and-pricing-of-narcan-naloxone-hcl-nasal-spray-4-mg/) The 2024 cost was trended to 2025 using a 2.9% annual trend. CHBRP assumed both prescription and nonprescription naloxone hydrochloride nasal spray would be available at this price.

Methodology and Assumptions for Baseline Cost Sharing

- For commercial enrollees, the following calculations were performed for prescription naloxone hydrochloride for HSA and non-HSA plans separately:
  - The paid-to-allowed ratios for prescription naloxone hydrochloride were calculated using the CHSD database.
  - To adjust for average plan benefit differentials by line of business, factors were calculated by comparing paid-to-allowed ratios of each line of business to the overall paid to allowed ratios of the California commercial population in the CHSD database.
  - The naloxone hydrochloride paid-to-allowed ratios were multiplied by the line of business factors to calculate line of business specific naloxone hydrochloride paid-to-allowed ratios.
  - One minus the line of business adjusted paid-to-allowed ratio was multiplied by the allowed cost to determine the enrollee share of cost.
- CHBRP assumed Medi-Cal plans have no cost sharing.

- CHBRP assumed commercial enrollees who use nonprescription naloxone hydrochloride at baseline pay the full cost of the drug.

Methodology and Assumptions for Postmandate Utilization

- CHBRP assumed the utilization rate for enrollees with coverage postmandate would remain the same or increase if the postmandate cost sharing maximum of $10 is less than the baseline cost sharing. The induced utilization factors were developed using the 2023 Milliman Health Cost Guidelines.
- Enrollees with an HSA-qualified policy would first need to meet the federal minimum deductible of $1600 before their cost sharing would be reduced to $10. CHBRP used 2021 CHSD trended to 2024 to estimate the percentage of HSA qualified high deductible health plan members who will exceed this deductible. CHBRP totaled medical and pharmacy claims for each member through the end of September and estimated 32% of HSA qualified high deductible health plan members would exceed $1,600 in total claims by the fourth quarter. CHBRP assumed 32% of HSA qualified high deductible health plan members would exceed the deductible portion of their plans before utilizing naloxone while 68% of members would not exceed the deductible portions of their plans.
- The 32% of enrollees with HSA qualified plans who met the $1600 deductible in the first 9 months were assumed to receive the cost sharing reduction to $10 copayment. The utilization of these enrollees increased accordingly, based on the induced utilization factors. The remaining enrollees in HSA qualified plans were assumed to pay the cost of naloxone hydrochloride in full, and their utilization remained unchanged from baseline.
- Because Medi-Cal plans do not have cost sharing, the prescription utilization rate for Medi-Cal enrollees remains unchanged postmandate.
- As mentioned above, the Substance Abuse and Mental health Services Administration reports 1.58% of Californians aged 12 and over have an opioid addition. (From AB1288, SAMHSA, 2023) CHBRP assumed 36% of those Californians were in commercial plans and 38% were in Medi-Cal plans. (From KFF 2019, https://www.kff.org/uninsured/issue-brief/key-facts-about-uninsured-adults-with-opioid-use-disorder/) CHBRP assumed 20% of Medi-Cal enrollees with an opioid addiction would receive one kit of nonprescription naloxone hydrochloride postmandate. CHBRP assumed 5% of Medi-Cal enrollees with an opioid addiction would have one family member who would also receive one kit of nonprescription naloxone hydrochloride.
- CHBRP assumed all nonprescription utilization for naloxone hydrochloride would be nasal spray.

Methodology and Assumptions for Postmandate Cost

- CHBRP assumed the average cost per script would not change as a result of AB 1060. CHBRP assumed all nonprescription utilization for naloxone would be nasal spray.

Methodology and Assumptions for Postmandate Cost Sharing

- CHBRP assumed a maximum of $10 cost sharing postmandate for prescription and nonprescription naloxone hydrochloride for enrollees not in HSA qualified high deductible health plans.
- CHBRP assumed a maximum of $10 cost sharing postmandate for prescription and nonprescription naloxone hydrochloride for HSA qualified health plan enrollees who reach $1,600 in claims prior to the final quarter of the year.
- CHBRP assumed HSA qualified health plan enrollees who do not reach $1,600 in claims prior to the final quarter of the year will have postmandate cost sharing equal to the postmandate cost.

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ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

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

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

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