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Analysis of California Assembly Bill 1060: Naloxone Hydrochloride

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Abbreviated Analysis

California Assembly Bill 1060: Naloxone Hydrochloride

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SUMMARY

The California Assembly Committee on Health requested that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of California Assembly Bill (AB) 1060. AB 1060 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, 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.

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 an 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).

Naloxone is commonly sold under the brand name Narcan.

Distribution of Naloxone

People in California can obtain naloxone with a prescription through a clinician, directly from a pharmacy, or through a community organization. Additionally, first responders, law enforcement, or others who possess naloxone can administer the medication to someone potentially experiencing an overdose. Access to and use of naloxone are two separate steps. Because someone experiencing an overdose is typically

unresponsive, they are not able to administer the medication to themselves, thereby requiring a second person.

Between October 2018 and March 2023, the Naloxone Distribution Project has distributed more than 2,200,000 kits of naloxone in California. Use of these kits have reversed more than 140,000 opioid overdoses. Most of the kits are obtained by harm reduction organizations (31%), law enforcement and criminal justice (17%), county health agencies (16%), and other community organizations (10%). Of the reported opioid reversals, 60% were reported by harm reduction organizations and 23% by county health agencies.

Access to and Use of Naloxone

It is challenging to estimate naloxone administration in the United States because of the various trained and untrained people who potentially administer it. Additionally, naloxone is frequently administered outside of the medical system, and recipients of naloxone administration may or may not seek medical care as follow up.

Studies have reported that among people who inject drugs, approximately three-quarters have received a kit of naloxone, half have received naloxone within the previous 6 months, and 35% report currently owning a dose of naloxone. Most of the population reported obtaining naloxone through syringe service programs.

Nationally, it is estimated that bystanders were present but unable to provide life-saving

measures in approximately half (46%) of fatal overdoses in 2021.

A study of opioid overdose survival in Pennsylvania found that naloxone was administered in 75% of survival cases and 29% of fatal overdose cases. People who were administered naloxone had 8.4 times greater odds of survival than those who did not receive naloxone.

Disparities in Access to Naloxone

The presence of disparities in access to naloxone exist, but vary, by race/ethnicity, geography, and housing status. While research does present disparities, some studies have found improved access for people of color or no difference by various characteristics.

Barriers to Accessing Naloxone for Opioid Overdose

Several substantial barriers to accessing naloxone exist: naloxone's current prescription-only status, insurance coverage including cost sharing and or prior authorization requirements, insurance prescription fill limits, physical location of the product (e.g., location of pharmacies or prevalence of naloxone distribution through community organizations), bias and stigma (i.e., requesting the drug from a health care professional or carrying the drug may imply illicit drug use), and systemic racism. Additional barriers to carriage have been identified, in addition to the barriers for access, including aspects of product design such as bulky packaging that may impede portability and stigma or identification as a person who uses drugs as a result of carrying naloxone.

There are some uncertainties regarding how nonprescription naloxone will be available. While nonprescription naloxone is able to be sold "over the counter," pharmacies or stores may decide to keep naloxone behind the pharmacist counter or behind protected glass, thereby requiring a shopper to ask for access to naloxone. Additionally, since AB 1060 would require insurance coverage without cost sharing for naloxone, it is unclear how this provision will be implemented. Enrollees whose health insurance would be subject to AB 1060 may, for example,

file for reimbursement from their insurer after paying out of pocket for naloxone at the time of purchase or may purchase naloxone through a pharmacy that is able to directly bill their insurance company. Options available to enrollees for obtaining naloxone free of charge will also enable or hinder access.

Relevant Population

If enacted, AB 1060 would apply to the health insurance of 24,853,000 California enrollees (64% of all Californians) (see Table 2). 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

Postmandate, 100% of the 24,982,000 enrollees will have coverage fully compliant with AB 1060, meaning prescription and nonprescription naloxone would be covered without cost sharing.

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.

CHBRP estimates that prescription naloxone (nasal sprays and injections) prescriptions will increase by 1,410 from 38,850 to 40,260, a 3.63% increase. Nonprescription naloxone (nasal sprays) covered by insurers will increase from 0 to 77,580. The increased utilization is driven both by the proposed legislation's removal of cost sharing as well as by removal of the need for a prescription. Because Medi-Cal plans do not have cost sharing, the prescription utilization rate for Medi-Cal enrollees remains unchanged postmandate.

In the illustrative example, AB 1060 would increase total net annual expenditures by \$9,218,000 or 0.006% for enrollees with DMHC-regulated plans and CDI-regulated policies. In this example, the figure is adjusted by a loss of \$860,000 from the cost sharing for covered benefits (deductibles, copayments, etc.) that the proposed legislation prohibits.

Public Health Impacts

CHBRP estimates AB 1060 would result in increased distribution of naloxone, which would contribute to increased treatment of opioid overdoses and a potential reduction in mortality. This estimate is supported by evidence that use of naloxone is medically effective in reversing opioid overdose and an increase in distribution of naloxone. However, CHBRP is unable to quantify the extent to which reductions in mortality would occur due to uncertainties about

the degree to which distribution of naloxone would occur postmandate. It stands to reason that AB 1060 would contribute to a decrease in fatalities from opioid overdose, although the extent to which this would occur is unknown.

The long-term impact depends on the extent to which reductions in cost sharing and prescription requirements will lead to increased access and whether that increased access will lead to increased use of naloxone to treat opioid use overdose. People whose lives are saved with naloxone treatment may have different cost trajectories than those modeled in the short term. After an overdose, an enrollee may be seen by emergency medical personnel, seen in an emergency department, or seek treatment for an opioid use disorder. All of these actions would result in additional health expenditures over time.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of the medical, financial, and public health impacts of forthcoming amendments to Assembly Bill (AB) 1060, Naloxone Hydrochloride, which would require coverage without cost sharing for prescription and nonprescription naloxone hydrochloride.

Bill-Specific Analysis of AB 1060, Naloxone Hydrochloride

Bill Language

AB 1060 would require coverage of prescription and nonprescription naloxone hydrochloride (naloxone), if 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, for prescription or nonprescription naloxone.

Naloxone is commonly sold under the brand name Narcan.

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

Relevant Populations

If enacted, AB 1060 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).

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

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

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.

Interaction With Existing State and Federal Requirements

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

¹ CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

California Policy Landscape

California law and regulations

The Statewide Naloxone Standing Order was issued by the state Public Health Officer in 2017, as permitted by current law, to “1) allow community organizations and other entities in California that are not currently working with a physician, to distribute naloxone to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist; and 2) allow for the administration of naloxone by a family member, friend, or other person to a person experiencing or reasonably suspected of experiencing an opioid overdose” (CDPH, 2022).² The California Civil Code also states that a person who is prescribed or possesses naloxone must receive training provided by an opioid overdose prevention and treatment training program. This training must include the cause of an opiate overdose, mouth to mouth resuscitation, how to contact appropriate emergency medical services, and how to administer naloxone.

Pharmacists can dispense naloxone without a prescription as authorized and in compliance with current law.³ Pharmacists are required to provide training to the recipient. Furnishing naloxone is a covered pharmacist service under Medi-Cal.⁴

Current law⁵ requires that when an opioid or benzodiazepine is prescribed to a patient, a prescriber must offer the patient a prescription for naloxone if one or more of the following conditions are met: prescription dosage is 90 or more morphine milligram equivalents of an opioid medications per day; opioid medication is prescribed within a year from the date a prescription for benzodiazepine was dispensed; or patient presents with an increased risk for opioid overdose, including a history of opioid overdose, a history of opioid use disorder, or is at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.

California Naloxone Distribution Project

The Naloxone Distribution Project through DHCS aids qualified organizations with accessing free naloxone (DHCS, 2023a). Organizations must have a prescription or standing order, which they can also obtain through DHCS. Qualified organizations include first responders, fire, and emergency medical services; law enforcement, courts, and criminal justice partners; community organizations, harm reduction organizations, veteran organizations, and religious organizations; schools, universities, and libraries; county public health or behavioral health agencies; organizations that serve unhoused populations; substance use recovery facilities; and hospitals and emergency departments (DHCS, 2023b).

Similar requirements in other states

All 50 states and the District of Columbia have laws that allow an individual to obtain naloxone without a prescription in some capacity (LAPPA, 2023). In 33 states, including California, there are standing orders, and in 14 states and the District of Columbia, a prescriber and a pharmacist can enter into a standing order agreement on their own terms. Fifteen states, including California, place some type of requirement on insurers regarding coverage of naloxone.

In Massachusetts, two bills (HB 1142, SB 667) introduced in 2023 would prohibit cost sharing for prescription and nonprescription naloxone.

² California Civil Code Section 1714.22.

³ Business and Profession Code Section 4052.01.

⁴ Welfare and Institutions Code 14132.968.

⁵ Business and Profession Code Section 741.

Federal Policy Landscape

U.S. Food and Drug Administration (FDA)

In November 2022, the FDA issued a Federal Register notice that included a preliminary assessment that certain naloxone drug products — up to 4 milligrams (mg) nasal spray and up to 2 mg autoinjector for intramuscular or subcutaneous use — may be approvable as safe and effective for nonprescription use (FDA, 2022). In February 2023, a government advisory committee voted unanimously to recommend that the nasal spray be sold and distributed without a prescription (Facher, 2023). 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.

Other recent actions taken by the FDA include (FDA, 2023):

- Guidance clarifying that certain Drug Supply Chain Security Act requirements do not apply to the distribution of naloxone to harm reduction programs during the Opioid Public Health Emergency;
- Development of a model Drug Facts Label, required for over-the-counter drug products, with easy-to-understand pictograms on how to use the drug; and
- Extending the shelf life of naloxone nasal spray from 24 months to 36 months.

Affordable Care Act

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 AB 1060 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).^{6,7}

Essential Health Benefits

In California, nongrandfathered⁸ individual and small-group health insurance is generally required to cover EHBs.⁹ In 2024, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.¹⁰

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

⁶ 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.

⁷ 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.

⁸ 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.

⁹ 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.

¹⁰ 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.

to provide coverage of nonprescription naloxone without cost sharing would exceed EHBs.¹¹ 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.

Cost Sharing

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses¹²). Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.¹³

¹¹ Personal communication with DMHC, March 28, 2023.

¹² Premiums are paid by most enrollees, regardless of their use of any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through the Covered California, or they receive benefits through Medi-Cal.

¹³ Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

BACKGROUND ON OPIOID USE DISORDER AND NALOXONE FOR OPIOID OVERDOSE

AB 1060 would require coverage of prescription and nonprescription naloxone hydrochloride (commonly referred to as naloxone or by its most common brand name, Narcan) without cost sharing for opioid overdose treatment.

Opioid Use Disorder

The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) defines opioid use disorder as “a problematic pattern of opioid use leading to clinically significant impairment or distress” and persons must meet at least two of the defined criteria within a 12-month period to receive a diagnosis (APA, 2013). In 2017, the U.S. Surgeon General declared the opioid crisis a U.S. public health emergency due to the escalating rates of opioid overdose, and related mortality and other harms (HHS, 2018).

Opioid use disorder¹⁴ prevalence in California was 1.58% among people aged 12 years and older in 2021 (SAMHSA, 2023).

Opioid Use Disorder–Related Mortality, Emergency Department Visits, and Hospitalizations

People with opioid use disorder are at a greater risk of mortality and premature mortality (Blanco et al., 2013). The Centers for Disease Control and Prevention (CDC) attributes the increase in premature mortality across the United States since 2013 to a significant increase in overdose deaths associated with illicitly manufactured synthetic opioids (fentanyl). Those using opioids obtained illegally (on the street) are unaware of variations in strength for every dose purchased; illicitly manufactured fentanyl appears to have remained a significant problem in 2020 (CDC, 2022a). Illicit fentanyl is also increasing in lethality, with the federal Drug Enforcement Agency (DEA) reporting that approximately 60% of fake prescription pills in 2022 contained a potentially lethal dose of fentanyl; this is a sharp increase from 2021 when an estimated 40% of fake prescription pills contained a potentially lethal dose of fentanyl (DEA, 2022).

In 2021, 7,175 Californians died from an opioid-related overdose, which was an increase of 119% from 2019 (CDPH, 2023). 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 (CDPH, 2023). Research has shown that patients who are discharged from emergency departments after an opioid-related overdose are at a high risk for mortality. The 1-year mortality after an overdose ranged from 5.3% to 5.5% (Weiner et al., 2022).

Table 2 shows opioid-related overdose mortality by race/ethnicity, sex, and age in California. Disparities in mortality, emergency department visits, and hospitalizations exist by race or ethnicity, gender, age, sexual orientation, and mental health status. Refer to CHBRP’s analysis of AB 1288, Medication Assisted Treatment, for a full discussion of disparities in opioid use disorder prevalence and mortality (CHBRP, 2023).

¹⁴ “Opioid use disorder is defined as meeting the criteria for heroin or pain reliever use disorder” (SAMHSA, 2023).

Table 2. Opioid-related Overdose Mortality, Emergency Department Visit, and Hospitalization Rates in Californians per 100,000 residents by Race/Ethnicity, Sex, and Age, 2021

	Mortality per 100,000 Californians	Emergency Department Visits per 100,000 Californians	Hospitalizations per 100,000 Californians
Overall annual rate	18	54	12
Race/ethnicity			
Black	34	100	24
Latino	14	38	9
American Indian/Alaskan Native	47	76	11
Asian/Pacific Islander	4	7	2
White	27	88	19
Sex			
Male	27	78	16
Female	8	29	8
Age			
15 to 19	9	43	9
20 to 29	54	226	34
30 to 39	73	236	39
40 to 49	50	120	24
50 to 64	77	129	52
65 to 79	24	53	51

Source: California Health Benefits Review Program, 2023; CDPH, 2023

Note: Rates rounded to the nearest whole number; Age-adjusted rates reported except for age category (crude rates).

Naloxone for Opioid 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). Naloxone is only effective for opioid overdose and has no effect on other common overdoses such as methamphetamines, benzodiazepines, or alcohol. When used for opioid overdose, naloxone takes effect within several minutes. As patients suffering from opioid overdose typically are unconscious and have very slow or no breathing, naloxone can rapidly reverse these conditions and lead to full consciousness and regular breathing within a few minutes. While a single dose of Naloxone is often effective, some patients may require several doses of naloxone to reverse the overdose (NIDA, 2022).

Even though Naloxone is extremely effective at reversing opioid overdoses, naloxone is not a definitive treatment. Naloxone only exerts its effects for approximately 30 to 90 minutes. Many opioids can last for several hours or longer, so repeat naloxone administration may be necessary after the initial naloxone wears off. Furthermore, while naloxone is extremely effective at preventing death and is generally safe, it is not without some side effects experienced by some patients. By quickly reversing the opioid overdose, naloxone rapidly induces opioid withdrawal symptoms. While these opioid withdrawal symptoms are rarely life threatening, they can include nausea, vomiting, tremors, agitation, and other uncomfortable symptoms. Naloxone does not cause any significant harm if administered to a person without opioid overdose (NIDA, 2022).

Forms of Naloxone

Naloxone is a medication that was first approved by the U.S. Food and Drug Administration (FDA) in 1971 for suspected opioid overdose (Adapt Pharma, 2015). Naloxone is a clear liquid that is available in both vials and prefilled containers, however the vials are typically used only by trained health care providers whereas the prefilled containers can be easily used by laypersons. Naloxone can be administered to a patient through a variety of routes, including intravenous (injection into a vein), intramuscular (injection into a muscle), or subcutaneous (injection into the skin layer). These methods all require a needle and some level of training in medication administration.

Though naloxone was initially only FDA approved for administration through these invasive routes, naloxone can also be administered with a noninvasive intranasal technique (spray administration into nostrils). In November 2015, the FDA formally approved naloxone as a standalone prefilled container with a pre-attached nasal spray applicator. Unlike previous naloxone formulations, this new formulation does not require assembly and is much more user-friendly (Adapt Pharma, 2015). As mentioned in the *Policy Context* section, the FDA formally approved the single dose nasal spray form of naloxone for nonprescription sale. Naloxone is commonly sold under the brand name Narcan. Other forms of naloxone for the public, such as the EVZIO auto-injector, remain accessible only with a prescription (Kaleo, 2016).

Distribution of Naloxone

As discussed in the *Policy Context* section, there are several ways in which someone with opioid use disorder or a community member can access naloxone. People in California can obtain naloxone with a prescription through a clinician, directly from a pharmacy, or through a community organization. Additionally, first responders, law enforcement, or others who possess naloxone can administer the medication to someone potentially experiencing an overdose. Access to and use of naloxone are two separate steps. Because someone experiencing an overdose is typically unresponsive, they are not able to administer the medication to themselves, thereby requiring a second person. Additionally, by definition, not all naloxone will be used since the premise of naloxone is to have a sufficient amount within the community in order to reduce the number of fatal opioid overdoses. Given that a substantial portion of naloxone in the community expires and is therefore unused, it is difficult to estimate the proportion of distributed naloxone that is actually used.

Between October 2018 and March 2023, the Naloxone Distribution Project (NDP) (see the *Policy Context* for discussion) has distributed more than 2,200,000 kits of naloxone in California (DHCS, 2023a). Use of these kits have reversed more than 140,000 opioid overdoses. Most of the kits are obtained by harm reduction organizations (31%), law enforcement and criminal justice (17%), county health agencies (16%), and other community organizations (10%). Of the reported opioid reversals, 60% were reported by harm reduction organizations and 23% by county health agencies. Law enforcement, community organizations, first responders (fire, EMS, and other), and homeless programs reported between 3% and 5% each.

A recent report commissioned by the FDA estimates that 16.95 million doses of naloxone were distributed in the United States in 2021 (Reagan-Udall Foundation, 2023). Approximately 2.64 million and 6.61

million doses were distributed to retail pharmacies and other health care facilities, respectively, while 7.7 million doses were distributed through other sources. Additionally, the nasal spray was the predominant form of naloxone distributed.

Access to and Use of Naloxone

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, and recipients of naloxone administration may or may not seek medical care as follow-up.

For persons presenting to the emergency department with an opioid overdose in Massachusetts and New Hampshire, less than half (43%) received at least one prescription for naloxone (Weiner et al., 2022).

A study among people who inject drugs (PWID) in Los Angeles and San Francisco reported that almost three-quarters (72%) of their population had ever received a kit of naloxone and about half have received naloxone within the previous 6 months (Kinnard et al., 2021). Among this same population, 35% reported currently owning a dose of naloxone. Three quarters of those who received naloxone in the previous 6 months reported using or losing their dose, and two-thirds of this group refilled their dose. Persons who used opioids were more likely to have received a dose of naloxone within the previous 6 months, as compared with those who reported no opioid use. Most of the population reported obtaining naloxone through syringe service programs. Similar results occurred within a pooled analysis; a pooled prevalence of 43% was observed for current ownership and a pooled prevalence of 52% was observed for ownership within the previous 12 months (Burton et al., 2021).

Similarly, Ong and coauthors (2020) reported PWID with prior prescription opioids abuse had four times the odds of access to naloxone. Access to drug treatment services increased PWID's odds of naloxone access five times. Prior naloxone administration also increased the odds of naloxone access but to a lesser degree. PWID reporting a hospital as a usual place for care were four times more likely to access naloxone relative to having no usual place for care. This study also found that factors associated with increased naloxone access include being unemployed, not having health insurance, and being homeless (Ong et al., 2020), although Kinnard and coauthors found that housed participants were more likely to possess naloxone (2021).

Nationally, it is estimated that bystanders were present but unable to provide life-saving measures in approximately half (46%) of fatal overdoses in 2021 (CDC, 2022b). A recent study in New York among PWID found between 8% and 16% of participants reported complete protection during opioid use, defined as having naloxone and another person present who is able to administer the naloxone (Khan et al., 2023). Burton et al.'s (2021) pooled analysis reported a 20% carriage rate, defined as either possession on day of interview or asking about regular carriage. However, the presence of a second person was not reported.

A study of opioid overdose survival in Pennsylvania found that naloxone was administered in 75% of survival cases and 29% of fatal overdose cases (Holmes et al., 2022). People who were administered naloxone had 8.4 times greater odds of survival than those who did not receive naloxone. Survival was higher among women, those under age 40, and Black persons as compared with White persons. A national review of the CDC's State Unintentional Drug Overdose Reporting System found that 77% of fatal opioid overdoses had no evidence of naloxone administration (Quinn et al., 2022).

Disparities¹⁵ in Access to Naloxone

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

Taken as a whole, prevalence and treatment of substance use disorders is inextricably linked bidirectionally with many important social determinants of health (SDOH). SDOH such as quality of a person's local built environment, proximity to crime, educational opportunities, self-efficacy, and income levels can influence a person's risk for substance use disorders (Mooney et al., 2018; Sudhinaraset et al., 2016). Conversely, substance use disorders can also alter a person's baseline SDOH through the consequences of the disorder, such as involvement with the criminal justice system, job loss, unstable housing or family situations, and discrimination against those with treated or untreated substance use disorder (Krebs et al., 2016).

The presence of disparities in access to naloxone exist, but vary, by race/ethnicity, geography, and housing status. While research does present disparities, other studies have found improved access for people of color or no difference by various characteristics.

Race or Ethnicity

Persons who identified as Latinx or Black were significantly less likely than White persons to receive naloxone in the past 6 months (Kinnard et al., 2021). Multiple studies have identified racial/ethnic disparities in access, training, and administration of naloxone (Khan et al., 2023). A recent study in New York found rates of currently possessing naloxone was higher in White participants (62%) as compared with Latinx (54%) or Black (48%) participants (Khan et al., 2023). Another study examining disparities in access to naloxone in Michigan found that being White was associated with increased access (Ong et al., 2020).

Weiner et al.'s 2022 study of naloxone prescription when a person in opioid overdose presents to the emergency department found that Hispanic people and those of "other" race/ethnicity were more likely to receive a prescription as compared with non-Hispanic White people. There was no significant difference in rates of prescription between non-Hispanic White people and Black people, or by gender or primary language.

Geography

Research has found that access to naloxone is higher for PWID in suburban/rural areas as compared with urban areas (Ong et al., 2020). In California, rates of naloxone distribution within the naloxone distribution program are higher in rural areas as compared with urban areas (DHCS, 2023a). Studies have also found that neighborhoods with a significantly higher proportion of White residents compared to Black residents had more pharmacies with naloxone in stock (Abbas et al., 2021).

Barriers to Accessing Naloxone for Opioid Overdose

Several substantial barriers to accessing naloxone exist. The Reagan-Udall Foundation's 2023 report mentions barriers such as naloxone's current prescription-only status, insurance coverage including cost sharing and or prior authorization requirements, insurance prescription fill limits, physical location of the product (e.g., location of pharmacies or prevalence of naloxone distribution through community

¹⁵ Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. (Wyatt et al., 2016).

organizations), bias and stigma (i.e., requesting the drug from a health care professional or carrying the drug may imply illicit drug use), and systemic racism. In California, even though naloxone is available from pharmacies without a prescription through the state's standing drug order, pharmacists are required to provide training to recipients of naloxone. San Diego County is installing a few "vending machines" that dispense naloxone, but users of the vending machine must take a training online before they can successfully obtain the naloxone; the vending machines are not intended for emergency use (Brennan, 2023).

Additional barriers to carriage have been identified, in addition to the barriers for access, including aspects of product design such as bulky packaging that may impede portability and stigma or identification as a person who uses drugs as a result of carrying naloxone (Burton et al., 2021).

Stigma, both from the person using opioids and from external people and systems, can pose substantial barriers to accessing and using naloxone (Martignetti and Sun, 2022). Additionally, prior studies have highlighted the "double stigma" of substance use and racism, negatively impacting the utilization of substance use treatment services (Scott and Wahl, 2011).

There are some uncertainties regarding how nonprescription naloxone will be available. While nonprescription naloxone is able to be sold "over the counter," pharmacies or stores may decide to keep naloxone behind the pharmacist counter or behind protected glass, thereby requiring a shopper to ask for access to naloxone. Additionally, since AB 1060 would require insurance coverage without cost sharing for naloxone, it is unclear how this provision will be implemented. Enrollees whose health insurance would be subject to AB 1060 may, for example, file for reimbursement from their insurer after paying out of pocket for naloxone at the time of purchase or may purchase naloxone through a pharmacy that is able to directly bill their insurance company. Options available to enrollees for obtaining naloxone free of charge will also enable or hinder access.

Societal Impact of Substance Use Disorder in California

The presence of substance use disorder in California has direct and indirect economic and societal costs. The California Department of Public Health estimates that substance use disorder in California produces an estimated economic loss of over \$230 billion annually. Illicit drugs and misuse of prescription opioids account for \$18 billion in direct health care costs (DHCS, 2013). The remaining \$155 billion accounts for indirect costs, such as lost work productivity and crime (NIDA, 2017). Please note, the societal impact discussed here is relevant to a broader population than AB 1060 impacts, which would affect the health insurance of a subset of Californians (see *Policy Context*). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of direct cost impacts for the specific population targeted by AB 1060.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 1060 would require coverage of naloxone hydrochloride (naloxone) without cost sharing, with or without a prescription. AB 1060 applies to enrollees in health plans and health policies regulated by DMHC¹⁶ or CDI as well as to beneficiaries in Medi-Cal.

This section presents an illustrative example of potential incremental impacts of AB 1060 on estimated baseline benefit coverage, utilization, and overall cost. As mentioned in the *Background on Opioid Use Disorder and Naloxone for Opioid Overdose* section, 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 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.

As mentioned in the *Background on Opioid Use Disorder and Naloxone for Opioid Overdose* section, 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.¹⁷

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

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 no enrollees have access to nonprescription naloxone at baseline. Cost sharing for prescription naloxone at baseline would be subject to an enrollee's prescription drug coverage benefit design. Postmandate, 100% of the 24,982,000 enrollees will have coverage fully compliant with AB 1060.

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

¹⁶ This includes approximately 73% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS).

¹⁷ See the *Policy Context* for information about the FDA's discussion of which naloxone products would be candidates for nonprescription approval.

prescription medications.¹⁸ 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

CHBRP estimates that use of prescription naloxone (nasal sprays and injections) will increase by 1,410 from 38,850 to 40,260, a 3.63% increase. Use of nonprescription naloxone (nasal sprays) covered by insurers will increase from 0 to 77,580. The increased utilization is driven both by the proposed legislation's removal of cost sharing as well as by removal of the need for a prescription. Because Medi-Cal plans do not have cost sharing, the prescription utilization rate for Medi-Cal enrollees would remain unchanged postmandate.

Baseline and Postmandate Per-Unit Cost

The cost per prescription for prescription naloxone (nasal sprays and injections) would increase by \$1 from \$118 to \$119 in postmandate. The \$1 cost increase is because of changes in enrollee mix; the actual cost of the prescriptions do not change. However, more commercial enrollees get prescriptions when cost sharing is removed (i.e., cost sharing = \$0), 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 \$95. The same dynamic as described previously applies. The cost per unit is the same but CHBRP assumes Medi-Cal RX enrollees use at the same rate as commercial patients (in prescriptions, the Medi-Cal utilization is lower).

Baseline and Postmandate Expenditures

Table 4 and Table 5 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

In the illustrative example, AB 1060 would increase total net annual expenditures by \$9,218,000 or 0.006% for enrollees with DMHC-regulated plans and CDI-regulated policies. In this example, the figure is adjusted by a loss of \$860,000 from cost sharing for covered benefits (deductibles, copayments, etc.) which the proposed legislation prohibits. There is no change expected in enrollee expenses for noncovered benefits.

Premiums

Changes in premiums as a result of AB 1060 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 3, Table 4, and Table 5), with health insurance that would be subject to AB 1060.

In the illustrative example, it is estimated that the mandate would increase premiums by about \$10.1 million. The distribution of the impact on premiums is as follows:

¹⁸ For more detail, see CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

- Total premiums for private employers purchasing group health insurance would increase by \$4,773,000, or 0.008%.
- Total employer premium expenditures for CalPERS HMOs would increase by \$340,000, or 0.006%.
- Enrollee contributions toward premiums for group insurance would increase by \$1,508,000, or 0.008%.
- Total premiums for purchasers of individual market health insurance would increase by \$2,129,000, or 0.010%.
- State expenditures for Medi-Cal would increase by \$1,328,000, or 0.003%.

Enrollee Expenses

AB 1060–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 3, Table 4, and Table 5) with health insurance that would be subject to AB 1060 that are expected to use the relevant benefit during the year after enactment.

In the illustrative example, CHBRP projects a change in copayments and coinsurance rates and does project an increase in quantities of naloxone and a change in enrollee cost sharing. In terms of enrollee out-of-pocket expenses, CHBRP predicts that cost sharing for covered benefits (deductibles, copayments, etc.) will decrease by \$860,000 or 0.006%.

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.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 3, Table 4, and Table 5), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1060.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 1060.

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 3. Impacts of AB 1060 on Benefit Coverage, Utilization, and Cost, 2024

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	24,982,000	24,982,000	0	0.00%
Total enrollees with health insurance subject to AB 1060	24,982,000	24,982,000	0	0.00%
Utilization and unit cost				
Prescription naloxone (nasal sprays and injections)				
Scripts	38,850	40,260	1,410	3.63%
Cost per script	\$118	\$119	\$1	0.57%
Average cost-share	\$22	\$0	-\$22	-100.00%
Nonprescription naloxone (nasal sprays)				
Scripts	0	77,580	77,580	100.00%
Cost per script	\$0	\$95	\$95	100.00%
Expenditures				
<i>Premiums</i>				
Employer-sponsored (b)	\$57,647,993,000	\$57,652,766,000	\$4,773,000	0.008%
CalPERS employer (c)	\$6,158,262,000	\$6,158,602,000	\$340,000	0.006%
Medi-Cal (d)	\$41,832,580,000	\$41,833,908,000	\$1,328,000	0.003%
<i>Enrollee premiums</i>				
Enrollees, individually purchased insurance	\$21,229,233,000	\$21,231,362,000	\$2,129,000	0.010%
Outside Covered California	\$4,867,955,000	\$4,868,440,000	\$485,000	0.010%
Through Covered California	\$16,361,278,000	\$16,362,922,000	\$1,644,000	0.010%
Enrollees, group insurance (e)	\$18,263,775,000	\$18,265,283,000	\$1,508,000	0.008%
<i>Enrollee out-of-pocket expenses</i>				
Cost sharing for covered benefits (deductibles, copays, etc.)	\$13,857,141,000	\$13,856,281,000	-\$860,000	-0.006%
Expenses for noncovered benefits (f)	\$0	\$0	\$0	0.000%
Total expenditures	\$158,988,984,000	\$158,998,202,000	\$9,218,000	0.006%

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.

Table 4. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (c) Under 65	65+	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	10,053,000	904,000	371,000	35,000	127,000	24,982,000
Total enrollees in plans/policies subject to AB 1060	7,780,000	2,212,000	2,618,000	882,000	10,053,000	904,000	371,000	35,000	127,000	24,982,000
Premium costs										
Average portion of premium paid by employer (e)	\$473.17	\$417.10	\$0.00	\$581.85	\$289.84	\$633.04	\$490.57	\$517.32	\$0.00	\$105,638,835,000
Average portion of premium paid by enrollee	\$122.17	\$180.13	\$645.33	\$113.49	\$0.00	\$0.00	\$180.61	\$168.99	\$626.90	\$39,493,007,000
Total premium	\$595.34	\$597.23	\$645.33	\$695.34	\$289.84	\$633.04	\$671.18	\$686.31	\$626.90	\$145,131,842,000
Enrollee expenses										
Cost-sharing for covered benefits (deductibles, copays, etc.)	\$40.98	\$127.06	\$168.73	\$49.17	\$0.00	\$0.00	\$99.22	\$184.48	\$208.51	\$13,857,141,000
Expenses for noncovered benefits (f)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$636.33	\$724.29	\$814.06	\$744.50	\$289.84	\$633.04	\$770.40	\$870.80	\$835.40	\$158,988,983,000

Source: California Health Benefits Review Program, 2023.

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

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.7% 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).

(c) 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.

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

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

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

Table 5. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (c) Under 65 65+		Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	10,053,000	904,000	371,000	35,000	127,000	24,982,000
Total enrollees in plans/policies subject to AB 1060	7,780,000	2,212,000	2,618,000	882,000	10,053,000	904,000	371,000	35,000	127,000	24,982,000
Premium costs										
Average portion of premium paid by employer (e)	\$0.0374	\$0.0414	\$0.0000	\$0.0322	\$0.0098	\$0.0134	\$0.0364	\$0.0471	\$0.0000	\$6,442,000
Average portion of premium paid by enrollee	\$0.0097	\$0.0179	\$0.0649	\$0.0063	\$0.0000	\$0.0000	\$0.0134	\$0.0154	\$0.0584	\$3,638,000
Total premium	\$0.0470	\$0.0593	\$0.0649	\$0.0384	\$0.0098	\$0.0134	\$0.0498	\$0.0625	\$0.0584	\$10,080,000
Enrollee expenses										
Cost-sharing for covered benefits (deductibles, copays, etc.)	-\$0.0037	-\$0.0072	-\$0.0081	-\$0.0030	\$0.0000	\$0.0000	-\$0.0054	-\$0.0083	-\$0.0084	-\$859,000
Expenses for noncovered benefits (f)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0434	\$0.0522	\$0.0568	\$0.0354	\$0.0098	\$0.0134	\$0.0444	\$0.0542	\$0.0501	\$9,220,000
Postmandate percent change										
Percent change insured premiums	0.0079%	0.0099%	0.0101%	0.0055%	0.0034%	0.0021%	0.0074%	0.0091%	0.0093%	0.0069%
Percent change total expenditures	0.0068%	0.0072%	0.0070%	0.0048%	0.0034%	0.0021%	0.0058%	0.0062%	0.0060%	0.0058%

Source: California Health Benefits Review Program, 2023.

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

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.7% 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).

(c) 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.

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

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

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

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 1060 would require coverage of prescription and nonprescription naloxone without cost sharing for enrollees in DMHC-regulated plans, CDI-regulated policies, and Medi-Cal.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact¹⁹ of AB 1060 on opioid overdose reversal and disparities. See *Long-Term Impacts* for discussion of premature death and economic loss.

Estimated Public Health Outcomes

Measurable outcomes relevant to AB 1060 include the number of doses of naloxone distributed and administered, as well as the number of treated opioid overdoses and potentially avoided fatalities.

As presented in the *Background on Opioid Use Disorder and Naloxone for Opioid Overdose* section, naloxone is very effective in reversing opioid overdose and people who receive naloxone during an overdose are almost nine times more likely to survive as compared to people who do not receive naloxone.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, additional prescription utilization of naloxone would occur due to the elimination of cost sharing and new use of naloxone would occur through nonprescription access.

However, due to lack of data, there are uncertainties regarding how distribution of, access to, and use of naloxone would change postmandate. There is additional uncertainty regarding how the increase in naloxone would be distributed across the population and whether it would be available to those who experience an overdose. In order for the increase in naloxone insurance coverage to result in a reduction of fatal overdoses, several steps need to occur: enrollees need to obtain naloxone (either with or without a prescription); enrollees need to be in possession of naloxone and carry the naloxone with them; if the enrollee is an opioid user, they are in possession of naloxone *and* a second person is present when using/or the enrollee is in possession of naloxone *and* present when someone else is using; the second person administers naloxone to reverse a potential overdose; the reversal is successful.

There are also unknowns about how AB 1060 would be implemented and to what extent naloxone will be available postmandate. As discussed in the *Background on Opioid Use Disorder and Naloxone for Opioid Overdose* section, there are gaps in where naloxone is stocked in pharmacies, and how pharmacies make naloxone available without a prescription could also aid or hinder access for enrollees.

In the first year postmandate, CHBRP estimates AB 1060 would result in increased distribution of naloxone, which would contribute to increased treatment of opioid overdoses and a potential reduction in mortality. This estimate is supported by evidence that use of naloxone is medically effective in reversing opioid overdose and an increase in distribution of naloxone. However, CHBRP is unable to quantify the extent to which reductions in mortality would occur due to uncertainties about the degree to which distribution of naloxone would occur postmandate. It stands to reason that AB 1060 would contribute to a decrease in fatalities from opioid overdose, although the extent to which this would occur is unknown.

¹⁹ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

Impact on Disparities²⁰

As described in the *Background on Opioid Use Disorder and Naloxone for Opioid Overdose* section, disparities in access to naloxone exist by race and ethnicity and geography, while other evidence of disparities is mixed. Within the first 12 months postmandate, CHBRP estimates AB 1060 would have an unknown impact on disparities.

This is due to *limited evidence* supporting increased distribution of naloxone postmandate and uncertainties regarding how naloxone would be distributed within the population. However, should naloxone distribution increase and reach persons for whom access was previously challenging, it is possible there could be improvements in disparities.

The impact of AB 1060 on reducing documented disparities (see the *Background on Opioid Use Disorder and Naloxone for Opioid Overdose* section) is unknown because data are unavailable to estimate changes in the distribution of, access to, and use of naloxone.

²⁰ For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: <https://www.chbrp.org/about/analysis-methodology/public-health-impact-analysis>.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 1060, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

To the extent that the proposed legislation leads to additional access to naloxone, CHBRP expects long-term (after initial 12 months) utilization and cost impacts. The long-term impact depends on the extent to which reductions in cost sharing and prescription requirements will lead to increased access and whether that increased access will lead to increased use of naloxone to treat opioid use overdose.

People whose lives are saved with naloxone treatment may have different cost trajectories than those modeled in the short-term. After an overdose, an enrollee may be seen by emergency medical personnel, seen in an emergency department, or seek treatment for an opioid use disorder. All of these actions would result in additional health expenditures over time.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts disparities, premature death, and economic loss.

In the case of AB 1060, CHBRP estimates that, to the extent distribution of, access to, and use of naloxone increases in the long-term, there would be additional reversals of opioid overdoses.

Impacts on Premature Death and Economic Loss

Premature death

Premature death, measured by years of potential life lost (YPLL), is often defined as death occurring before the age of 75 years (NCI, 2019).²¹ In California, it is estimated that there were nearly 5,300 years of potential life lost (YPLL) per 100,000 population each year between 2015 and 2017 (CDPH, 2019).²² Overdose deaths, injuries/accidents, chronic diseases, and violence related to opioid use disorder are contributing factors to that rate.

Opioid-related mortality is considered a public health crisis, with more than 2,000 unintentional opioid deaths occurring in California in 2016 (Clemans-Cope et al., 2018; HHS, 2018). In terms of years-of-life-lost (YLL), Gomes et al. estimated the national burden of opioid deaths in 2016 represented 1 in 65 deaths (5.2 YLL/1,000 population), or about a quarter of the YLL due to cancer, the second leading cause of death in the United States. Males experience twice the rate of YLL as females (7.0 YLL/1,000 population versus 3.4 YLL/1,000 population); and the opioid-related YLL for males aged 25 to 34 years

²¹ For more information about CHBRP's public health methodology, see <https://www.chbrp.org/about/analysis-methodology/public-health-impact-analysis>.

²² The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Gardner and Sanborn, 1990).

(18.1/1,000 population) represented about a quarter of all YLL in the United States in 2016 (Gomes et al., 2018).

The quantitative long-term impact of AB 1060 on premature death associated with opioid use disorder is unknown; however, for persons who experience an opioid overdose who receive naloxone to reverse the overdose due to the increased distribution of naloxone, there likely will be a reduction in premature deaths.

APPENDIX A TEXT OF BILL ANALYZED

The California Assembly Committee on Health requested that CHBRP analyze AB 1060 as amended on March 16, 2023.

ASSEMBLY BILL

NO. 1060

Introduced by Assembly Member Ortega
(Coauthors: Assembly Members Arambula and Haney)
(Coauthor: Senator Wahab)

Amended March 16, 2023

An act to ~~amend Section 1797 of the Health and Safety Code, relating to emergency medical services.~~ *add Section 1374.198 to the Health and Safety Code, to add Section 10127.22 to the Insurance Code, and to add Section 14132.37 to the Welfare and Institutions Code, relating to opioids.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1060, as amended, Ortega. ~~Emergency medical services.~~ *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 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. The bill would require a health care service plan contract or health insurance policy, as specified, to include coverage for that same medication 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.

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.

~~Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, establishes the Emergency Medical Services Authority. Under existing law, the authority is responsible for the coordination and integration of all state activities concerning emergency medical services.~~

~~This bill would make technical, nonsubstantive changes to those provisions.~~

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

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 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 health care service plan contract that is issued, amended, delivered, or renewed on or after January 1, 2024, 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.*

SEC. 3. *Section 10127.22 is added to the Insurance Code, immediately following Section 10127.20, to read:*

10127.22. *A health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2024, 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.*

SEC. 4. *Section 14132.37 is added to the Welfare and Institutions Code, immediately following Section 14132.36, to read:*

14132.37. *Prescription or nonprescription naloxone hydrochloride 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.*

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

~~SECTION 1. Section 1797 of the Health and Safety Code is amended to read:~~

~~1797. This division shall be known, and may be cited, as the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act.~~

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.²³ 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.²⁴

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 all individuals have baseline coverage for prescription naloxone and all individuals have no baseline coverage for nonprescription naloxone.

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).

²³ 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.

²⁴ 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*.

- The commercial utilization rates were trended from 2021 to 2024 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 using a 1.0% annual trend.
- CHBRP assumed no utilization of nonprescription naloxone in the baseline.

Methodology and Assumptions for Baseline Cost

- CHBRP calculated the California average commercial cost per script of naloxone using 2021 CHSD database.
- The average commercial cost per script was trended from 2021 to 2024 using a 2.9% annual trend.
- The 2024 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).

Methodology and Assumptions for Baseline Cost Sharing

- The paid-to-allowed ratios for prescription naloxone 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 paid-to-allowed ratios were multiplied by the line of business factors to calculate line of business specific naloxone 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.

Methodology and Assumptions for Postmandate Utilization

- 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 reports 1.58% of Californians aged 12 and over have an opioid addiction (SAMHSA, 2023). CHBRP assumed 20% of enrollees with an opioid addiction would receive one kit of nonprescription naloxone postmandate. CHBRP assumed 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.

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 no cost sharing for prescription and nonprescription naloxone postmandate.

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

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 1060 would have a substantially different impact on utilization of either the

tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of AB 1060 would be substantially the same as the impacts in the first year (see Table 3). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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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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