

Key Findings

Analysis of California Senate Bill 854 Health Care Coverage: Substance Use Disorders

Summary to the 2019–2020 California State Legislature, March 15, 2020



AT A GLANCE

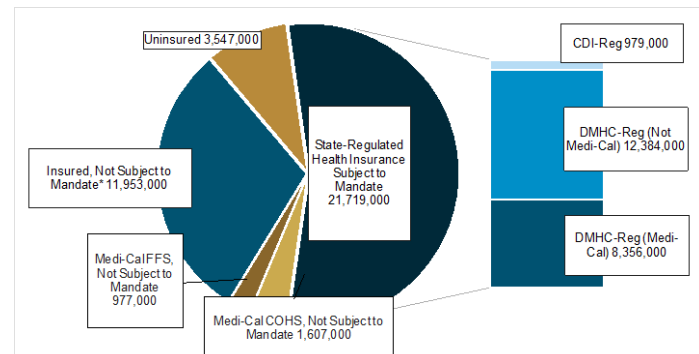
For commercial/CalPERS enrollees with coverage for outpatient prescription medications, Senate Bill (SB) 854 would require on-formulary, low-tier coverage of Food and Drug Administration (FDA) approved substance use disorder (SUD) medications and would prohibit some utilization management. It would also prohibit requiring prior authorization for coverage of counseling, the behavioral health treatment used “in conjunction” with those medications. In 2020, 62% of the 21.7 million Californians enrolled in state-regulated health insurance would have health insurance required to comply with SB 854.

1. **Benefit coverage.** Approximately 94% of commercial/CalPERS enrollees would see some change to their benefit coverage – primarily movement of some FDA approved SUD medications to a lower formulary tier.
2. **Utilization.** Commercial/CalPERS enrollee utilization would increase for many of these medications. There would be a shift between formulations of an opioid overdose reversal medication (naloxone) to greater use of the more costly auto-injector, as well as a shift from a medication used off-label for withdrawal symptoms (clonidine) to the more costly brand-name alternative (lofexidine). Increases in some related services (counseling) and decrease in others (inpatient days) would also occur.
3. **Expenditures.** Premium increases (less than 0.1%) and a decrease (less than 0.1%) in total enrollee out-of-pocket expenses for covered benefits (cost sharing) would occur.
4. **Medical effectiveness.** When successfully used as prescribed and directed, clear and convincing evidence indicates that many (but not all) FDA-approved SUD medications are effective. The effectiveness of in conjunction counseling is varies by SUD and is sometimes ineffective.
5. **Public health.** Barriers to treatment, limited patient willingness, and relapses will be limiting factors, but desirable health outcomes are expected for patients who successfully engage in treatment.

BILL SUMMARY

Senate Bill (SB) 854 would be applicable to plans and policies regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). SB 854 would exempt from compliance DMHC-regulated plans enrolling Medi-Cal beneficiaries. Figure A notes the variation in health insurance among Californians. SB 854 would require plans and policies that include a pharmacy benefit to place all medications approved by the federal Food and Drug Administration (FDA) and indicated for treatment of substance use disorders (SUDs) on the formulary’s lowest tier. SB 854 would also prohibit application of step therapy (“fail first”), prior authorization, and some other utilization management protocols for the coverage of these FDA-approved SUD medications. In addition, SB 854 would prohibit application of prior authorization protocols to the coverage of behavioral health services that are “in conjunction” with the FDA-approved SUD medications.

Figure A. Health Insurance in CA



Source: CHBRP 2020.

Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

In order to analyze the impacts of SB 854, CHBRP has made several analytic assumptions, including that benefit coverage requirements: (1) would be applicable to both prescription medications generally covered through a pharmacy benefit and to medications requiring a clinician for administration, but not would not be applicable to over-the-counter medications; (2) would be applicable to covered brand-name as well as generic medications; and (3) would be applicable to all covered formulations of the medications. CHBRP has also assumed that three forms of outpatient counseling (individual, family, and group) are the “in conjunction”

with FDA-approved SUD medications” behavioral therapy for which coverage would be impacted by SB 854. Although use of other forms of behavioral health concurrent with use of FDA-approved SUD medications is not uncommon, other forms are not commonly used specifically to support compliant use of the outpatient medication – and so CHBRP has assumed that coverage for other forms not be affected by SB 584.

Should SB 854 affect the coverage of other forms of behavioral health, such as the more structured and facility based partial hospitalization or intensive outpatient therapy, the various forms of residential treatment, or detox admissions, impacts would be orders of magnitude greater that projected in this report.

CONTEXT¹

There are 11 prescription-only FDA-approved SUD medications, with one pair available in a combination format (buprenorphine-naloxone) and several available in more than one formulation (injected/pill, nasal spray/inhaler, etc.). The SUDs are opioid use disorder, alcohol use disorder, and tobacco use disorder.

However, treatments for SUDs are not limited to medications, and frequently also include residential, inpatient, and outpatient care using behavioral health counseling and/or medication, as well as mutual help groups (e.g., Alcoholics Anonymous).

Structural and attitudinal barriers to accessing any treatment for opioid use disorder, alcohol use disorder, and tobacco use disorder affect use. Structural barriers include being uninsured, utilization management protocols when insurance is present, limited provider supply, and geographic access difficulties. Attitudinal barriers include limited patient receptiveness to treatment. For many with these disorders, attitudinal barriers are the most significant barrier to treatment initiation and persistence. The stigma of addiction and the ability to acknowledge an addiction affects patient desire to seek care. Many people with opioid use disorder and/or alcohol use disorder believe they can solve the problem themselves. Similarly, limited patient readiness for treatment is also a barrier for those with tobacco use disorder: a quarter of California smokers are not interested in quitting.

Currently, CHBRP estimates that only 13.0% of commercial/CalPERS enrollees with opioid use disorder take FDA-approved SUD medications. This underuse is not necessarily related to insurance coverage for

treatment and is more likely due to other factors, such as limited willingness to enter treatment.

Similarly, only 5.0% of commercial/CalPERS enrollees with alcohol use disorder and only 5.4% of those with tobacco use disorder use take prescription-only FDA-approved SUD medications. This underuse is linked to provider practice (limited prescribing), limited willingness to enter treatment, and other treatment options that do not rely on prescription medications (e.g., over-the-counter nicotine replacement therapy, Alcoholics Anonymous).

It should be noted, as well, that even when a patient is willing, treatment adherence is difficult. Relapse rates for patients in treatment for alcohol use disorder and opioid use disorder are significant and multiple quit attempts before successful cessation is common for tobacco use disorder.

IMPACTS

Medical Effectiveness

This analysis focuses on the effectiveness the of FDA-approved SUD medications, with or without behavioral health counseling, as treatments for opioid use disorder, alcohol use disorder, or tobacco use disorder.

Effectiveness is considered through studies of outcomes and studied outcomes vary depending on the SUD. Opioid use disorder outcomes include opioid use, participation in treatment, and mortality. Alcohol use disorder outcomes include alcohol use and participation in treatment. Tobacco use disorder outcomes include reduced cigarette cravings and abstinence.

The evidence is related to use of the medications when prescribed and used as directed. As indicated in the prior discussion of structural and attitudinal barriers to treatment, as well as limited patient willingness to enter treatment and the frequency of relapse and the need for repeated tries among patients who do, many patients have difficulty “using as directed” for the recommended period.

For prescription-only medications approved by the FDA for opioid use disorder:

- There is *clear and convincing* evidence that methadone, buprenorphine, and buprenorphine-naloxone are effective.

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

- There is *limited* evidence that injectable naltrexone is effective.
- There is a *preponderance* of evidence that orally administered naltrexone is not effective.
- Evidence comparing medications is *limited* or *inconclusive*.
- Evidence comparing medications with medications and counseling is *inconclusive*.
- There is *insufficient* evidence to compare lofexidine (brand-name only) and off-label use of clonidine (generic available).
- Evidence comparing the auto-injector formulation of naloxone with other formulations is *inconclusive*.

For prescription-only medications approved by the FDA for alcohol use disorder:

- There is *clear and convincing* evidence that acamprosate and naltrexone are effective.
- There is limited evidence that disulfiram is not effective.
- Evidence comparing medications is *inconclusive*.
- There is *limited* evidence that medications and counseling is no more effective than medications alone.

For prescription-only medications approved by the FDA for tobacco use disorder:

- There is *clear and convincing* evidence that prescription medications are effective.
- There is a *preponderance* of evidence favoring varenicline over nicotine replacement therapy (NRT).
- There is a *preponderance* of evidence that there is no different between NRT and bupropion.
- There is *limited* evidence that medications with counseling are more effective than medications alone.

Benefit Coverage, Utilization, and Cost

For this analysis, CHBRP has estimated the impacts of requiring tier 1 formulary coverage for the 11 FDA-approved SUD medications, and prohibiting the application of prior authorization, step therapy (“fail first”), and other utilization management protocols. CHBRP also considered the impact of prohibiting prior authorization for the coverage of in conjunction behavioral counseling.

Benefit Coverage

Approximately 94% of commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit that would need some alteration to be compliant with SB 854 - primarily a shift to a lower formulary tier for some FDA-approved SUD medications.

Most commercial/CalPERS enrollees have on-formulary coverage for most of the FDA-approved SUD medications; all would, postmandate. Few of these enrollees have tier 1 (or no) cost sharing for most brand-name versions of these medications; all would, postmandate. Few of these enrollees have prior authorization or step therapy protocols applicable to their coverage for these medications; none would, postmandate.

SB 854’s prohibitions regarding limited numbers of visits, days, scope, or duration - on coverage for outpatient medications - seem unlikely to have any measurable impact.

All commercial/CalPERS enrollees currently have coverage for behavioral counseling in conjunction with prescribed medication for opioid use disorder, alcohol use disorder, or tobacco use disorder that is not subject to prior authorization protocols. Therefore, 100% of enrollees currently have benefit coverage that meets the behavioral counseling portion of the SB 854 mandate.

Utilization

Use of most FDA-approved SUD medication and in conjunction behavioral health counseling is expected to increase, as is the expected number of users. The broad indirect impacts SB 854 would have are decreased inpatient days and emergency room use.

Generally, more users of the FDA-approved SUD medications among commercial CalPERS enrollees would be expected and use would increase by 10% (from the current users premandate rate). The exceptions and notes regarding shifts follow:

- The increased use of the brand-name formulation of lofexidine (used to manage opiate withdrawal symptoms) would accompany a decreased use of off-label generic clonidine.
- Within the increased use of naloxone for opioid use disorder (used to treat overdoses) there would be shift such that the more costly auto-injector formulation would represent half of all filled prescriptions.
- No utilization increase is expected for methadone for opioid use disorder because it is only delivered through federally certified centers.²
- No utilization increase is expected for disulfiram for alcohol use disorder, as providers have concerns regarding its lack of effectiveness.
- No utilization increase is expected for the nasal spray formulation of nicotine replacement therapy for tobacco use disorder, as it is not well-accepted by patients.

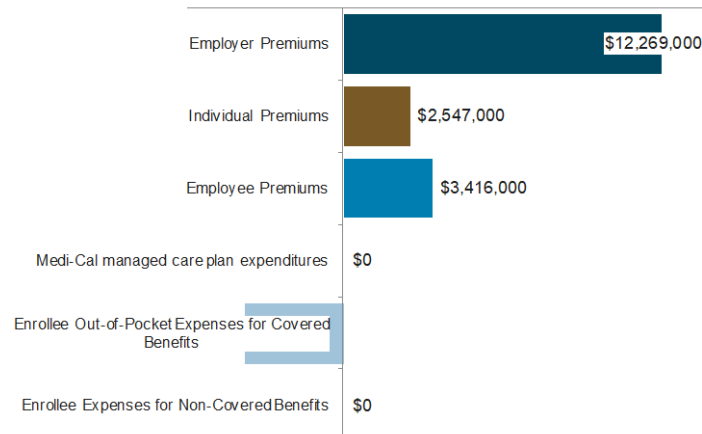
An increase in use in conjunction counseling would be expected among commercial/CalPERS enrollees using FDA-approved SUD medications.

Decreases in some related treatments and services would occur for some new (but not continuing) users of these medications. For new users of medications for opioid use disorder and alcohol use disorder, reductions in inpatient days, detox days, and emergency department visits would be expected.

Expenditures

The premium impacts noted in Figure B, represent an increases of less than 0.1% for all market segments and less than a 0.1% decrease in enrollee out-of-pocket expenses (cost sharing) for covered benefits.

Figure B. Expenditure Impacts of SB 854



Source: CHBRP, 2020.

Cost sharing impacts vary by market segment. Among commercial/CalPERS enrollees with on-formulary benefit coverage at baseline, the number of enrollees who will be impacted ranges from a low of 0.190% for CalPERS HMO to a high of 0.206% for small group DMHC-plans or CDI-regulated policies. For these enrollees, average annual out-of-pocket expenses are expected to decrease by a range of \$118.15 to \$128.75. Among commercial/CalPERS enrollees who gained on-formulary benefit coverage, the percent of enrollees who would be affected ranges from 0.035% for CalPERS HMO to 0.089% for individual plans. These enrollees are projected to have an increase in annual out-of-pocket expenses for medications, with or without behavioral counseling, by a range of \$108.14 to \$115.43. It should be noted that the per-user annual impact in the form of cost sharing savings (for commercial/CalPERS enrollees currently covered, whose medications will be mandated to be covered with Tier-1 cost sharing) and new spending (for enrollees with new access to these medications).

CalPERS

CalPERS premiums would be expected to increase less than 0.1%.

Number of Uninsured in California

No measureable impact is expected.

² Federal law restricts methadone treatment to federally certified opioid treatment programs (OTP), known as

methadone clinics, see Title 42 of the Code of Federal Regulations Part 8 (42 CFR § 8)

Public Health

In the first postmandate year, CHBRP estimates the following public health impacts:

Approximately 5,253 commercial/CalPERS enrollees with opioid use disorder and newly compliant benefit coverage would take FDA-approved substance use disorder medications, though 40% to 60% of them may experience relapse. Successful use of these medications would mean reducing illicit opioid use, opioid overdose and associated mortality, transmission of hepatitis C and HIV, and poor maternal-infant outcomes. Among those new users, SB 854 would also increase maintenance treatment retention and increase overdose reversals (through the use of naloxone).

Approximately 2,995 commercial/CalPERS enrollees with alcohol use disorder and newly compliant benefit coverage would take FDA-approved SUD medications, though 50% or more may experience relapse. Health outcomes of successful treatment would include reducing alcohol consumption and decreases in undesirable outcomes such as injuries/accidents and poor pregnancy outcomes.

Approximately 2,871 commercial/CalPERS enrollees with newly compliant benefit coverage would take FDA-approved tobacco use disorder medications, though some of them will relapse. Health outcomes of successful treatment would include increasing quit rates and sustaining abstinence, as well as decreases in undesirable outcomes, such as poor birth outcomes and smoking-exacerbated conditions (e.g., asthma and heart attacks).

Long-Term Impacts

Long-term utilization of FDA-approved medications for opioid use disorder could increase as opioid use disorder prevalence increases in the state. CHBRP estimates that the level of use per user per year predicted in 2021 would not change over time, but utilization overall would increase with additional use of opioids. Due to continuing structural and attitudinal barriers, CHBRP expects the portion of persons with opioid use disorder in treatment to remain limited, even as the total number of these persons increases. In the case of alcohol use disorder and tobacco use disorder

treatment, there is very low baseline utilization of the FDA-approved medications for the two conditions. Because plans reported few restrictions to obtaining these medications, it appears physicians and patients are not using them frequently to treat alcohol use disorder or tobacco use disorder and therefore CHBRP does not expect long-term changes.

A key barrier to treatment for any substance use disorder is patient interest and readiness. CHBRP anticipates the demand for treatment would continue as relapsed patients attempt treatment again and first-time initiators join the pool of patients seeking care. SB 854 would continue to facilitate prescription medication treatment for some enrollees (whose insurance did not previously offer compliant benefit coverage), but limited patient readiness for substance use disorder treatment and the demand-supply mismatch for regarding treatment for opioid use disorder and alcohol use disorder are likely to remain significant barriers to care in future years.

However, although the quantitative long-term impact of SB 854 on premature death associated with SUDs is unknown, it stands to reason, based on the effectiveness of FDA-approved substance use disorder medications, that there would be a reduction in premature deaths for those enrollees who successfully engage in treatment.

Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts

SB 584 would increase utilization of effective medications for tobacco use disorder among commercial/CalPERS enrollees, but would not do so among Medi-Cal beneficiaries enrolled in DMHC-regulated plans. As people of color are over-represented among Medi-Cal beneficiaries, an increase in disparate health outcomes among racial/ethnic groups is likely, should SB 854 become law.

Essential Health Benefits and the Affordable Care Act

SB 854 would alter the terms and conditions of existing benefit coverage, but would not require coverage for a new benefit and so appears unlikely to exceed the definition of EHBs in California.