Key Findings:

Analysis of California Senate Bill 11
Mental Health Parity and Substance Use Medications

Summary to the 2019–2020 California State Legislature, February 13, 2019

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

The version of California SB 11 analyzed by CHBRP would, for many enrollees in state-regulated plans and policies, require on-formulary, lowest tier coverage of prescription medications approved by the FDA for treatment of substance use disorders (SUDs). CHBRP estimates that, in 2019, of the 23.4 million Californians enrolled in state-regulated health insurance, 100% will have insurance that required to comply with SB 11.

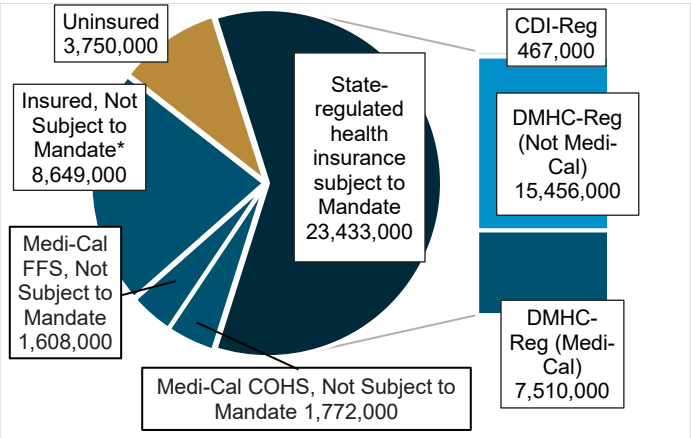
1. **Benefit coverage.** Approximately 93% of commercial and CalPERS enrollees and all Medi-Cal enrollees (beneficiaries enrolled in DMHC-regulated plans) would see some change to their benefit coverage.
2. **Utilization.** Among commercial and CalPERS enrollees, utilization would increase for many of the 13 medications approved by the FDA for SUD treatment. Among all enrollees, a shift to use of the more costly auto-injector formulation of naloxone (the opioid anti-overdose medication) would be expected. 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 most prescription-only medications approved by the FDA for treatment of SUD are effective.
5. **Public health.** Barriers to treatment, limited patient willingness, and relapses will limit impacts, but positive health outcomes are expected for patients who engage in treatment.
6. **Long-term impacts.** Increased rates of OUD may increase related impacts - but barriers to treatment, limited patient willingness, and relapse will continue to be limiting factors for impacts related to all three SUDs.

BILL SUMMARY

SB 11 has other aspects but also includes a benefit mandate, which CHBRP was asked to analyze. The benefit mandate would require plans and policies regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) that include a pharmacy benefit that covers outpatient prescription medications related to treatment of substance use disorders (SUDs) to place all medications approved by the federal Food and Drug Administration (FDA) and indicated for treatment of SUDs on formulary and on the formulary's lowest tier and, for those medications, prohibit prior authorization and step therapy (or "fail first") protocols. In addition, SB 11 would prohibit coverage denials for these medications, for counseling, and for "other wrap-around services" if the denial was related to a court order for treatment.

Figure A notes how many Californians have health insurance that would be subject to SB 11.

Figure A. Health Insurance in CA and SB 11



Source: California Health Benefits Review Program, 2019.
Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

In order to analyze the impacts of SB 11, CHBRP has made several analytic assumptions, including that benefit coverage requirements (1) would be applicable to prescription-only medications generally covered through a pharmacy benefit — so not applicable to over-the-counter medications or to medications requiring a clinician for administration and so generally covered through a medical

benefit; (2) would be applicable to covered brand name as well as generic medications; (3) would be applicable to all covered formulations of the medications.

CONTEXT[1]

The FDA has approved and indicated 10 prescription-only outpatient medications for treatment of three SUDS: opioid use disorder (OUD), alcohol use disorder (AUD), and/or tobacco use disorder (TUD).

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

Structural and attitudinal barriers to accessing any treatment for OUD, AUD, and TUD 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 OUD, AUD, and TUD, 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 OUD and/or AUD believe they can solve the problem themselves. Similarly, limited patient readiness for treatment is also a barrier for those with TUD: 33% of California smokers are not interested in quitting.

Prior to SB 11, CHBRP estimates that only 20% (one-fifth) of enrollees in plans and policies regulated by DMHC or CDI with OUD use FDA approved and indicated medications for OUD. This underuse is not necessarily related to insurance coverage for treatment and is more likely due to other factors, including other structural barriers (such as limited numbers of providers) and limited willingness to enter treatment. Prior to SB 11, less than 1% of enrollees with AUD or TUD use these 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 AUD and OUD are significant, and multiple quit attempts before successful cessation is common for TUD.

IMPACTS

Medical Effectiveness

As noted, there a multiple treatments for SUD, but this analysis focuses on the effectiveness the treatment addressed by SB 11: use of prescription-only outpatient medications approved by the FDA and indicated as treatments for OUD, AUD, and/or TUD that are generally covered through a pharmacy benefit.

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

The evidence is related to use of the medications when prescribed and used as directed. As already noted, many persons with OUD, AUD, or TUD have difficulty "using as directed" for the recommended period due to structural and attitudinal barriers to treatment. In addition, many people relapse and need to receive treatment repeatedly to abstain from using opioids, alcohol, or tobacco. However, for prescription-only medications approved by the FDA for OUD used as directed for the recommended period:

- There is *clear and convincing* evidence that methadone, buprenorphine, and buprenorphine-naloxone are effective
- There is a *preponderance* of evidence that orally administered naltrexone is not effective.
- Evidence comparing medications *is inconclusive*.

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

For prescription-only medications approved by the FDA for AUD:

- 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*.

For prescription-only medications approved by the FDA for TUD:

- 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 difference between NRT and bupropion.

Benefit Coverage, Utilization, and Cost

For this analysis, CHBRP has estimated the impacts of requiring on-formulary coverage for the 13 prescription-only outpatient medications approved by the FDA and indicated as treat one or more of three SUDs, prohibiting the application of prior authorization or step therapy ("fail first") protocols, and requiring tier 1 or lower cost sharing.

As CHBRP is unaware of coverage denials related to court orders, no measurable impact related to the SB 11 prohibition is expected.

Benefit Coverage

Approximately 95.6% of enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit that would need to be altered to be compliant with SB 11.

Most commercial and CalPERS enrollees have on-formulary coverage for most of these medications; all would postmandate. Few of these enrollees have tier 1 (or no) cost sharing for most brand-name 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.

All Medi-Cal beneficiaries enrolled in DMHC-regulated plans have coverage for these medications — though for OUD and AUD medications it is through a "carve-out" to the Medi-Cal fee-for-service (FFS) program. Excepting only coverage for the more costly auto-injector formulation of naloxone for OUD (the anti-overdose drug), the FFS program coverage is compliant with SB 11. Postmandate, these enrollees would have coverage from their DMHC-regulated plans as well, including SB 11–compliant naloxone coverage.

Utilization

Table 1 provides mediation specific impacts on expected use and on the expected number of users, as well as the broad indirect impacts SB 11 would have on counseling, inpatient days, and emergency room use.

Generally, use of the medications would increase among commercial enrollees and enrollees associated with CalPERS – and new users would be expected for some of the medications. The exceptions are:

- No utilization increase is expected for lofexidine for OUD (used to treat short-term withdrawal symptoms), as the medication is newly approved and not likely to be much prescribed by providers during the initial year after implementation of SB 11.
- Within the increased utilization of naloxone for OUD (used to treat overdoses) there would be a shift such that the more costly auto-injector formulation would represent half of all filled prescriptions.
- No utilization increase is expected for methadone for OUD because it may only be prescribed and delivered through federally certified centers,[2] which do not bill for medication alone (as would be covered by an SB 11–compliant pharmacy benefit).

[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)

- No utilization increase is expected for disulfiram for AUD, as providers have concerns regarding its lack of effectiveness.

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans almost all use would be unchanged, as the new SB 11–compliant coverage would be almost identical to their current coverage through the Medi-Cal FFS carve-out program. However, use of naloxone for OUD would shift towards the more costly auto-injector formulation because patients prefer it to other formulations of naloxone. The shifted utilization would be covered by the beneficiaries' newly SB 11–compliant plan (rather than to the existing FFS carve-out program).

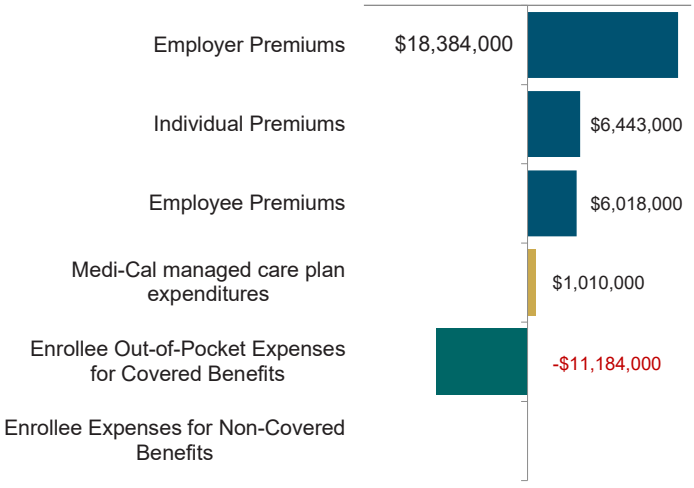
A 12.5% increase in use of related counseling would be expected among all enrollees using OUD and AUD medications.

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 OUD and AUD, reductions in inpatient days, detox days, and emergency department visits would be expected.

Expenditures

As noted in Table 1 and Figure B, SB 11 would result in premium increases of less 0.1% for all market segments less than a 0.1% decrease in total enrollee out-of-pocket expenses (cost-sharing) for covered benefits.

Figure B. Expenditure Impacts of SB 11



Source: California Health Benefits Review Program, 2019.

Cost-sharing impacts among enrollees using the medications would range from no impact (for Medi-Cal beneficiaries, who have no premandate cost sharing) to an average annual decrease of $418.28 among enrollees in individual market plans and policies.

Medi-Cal

Medi-Cal impacts related to OUD and AUD would be related only to a shift of naloxone for OUD (for overdose treatment) use to the more costly auto-injector formulation. Otherwise, the Medi-Cal FFS program provides SB11-compliant coverage, but SB 11 would make the auto-injector more easily accessible through DMHC-regulated plans. Some impact would be expected due to plans changing benefit coverage for TUD medications (which are not part of the Medi-Cal FFS carve out) to be compliant with SB 11.

CalPERS

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

Number of Uninsured in California

No measureable impact is expected.

Public Health

In the first postmandate year, CHBRP estimates the following public health impacts. As enrollees may use more than one medication, these enrollee estimates reflect an upper bound.

Approximately 3,100 enrollees with newly compliant benefit coverage would use FDA-approved OUD medications, though 40% to 60% may experience relapse. Health outcomes related to successfully use of these medications may include 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 11 would also increase maintenance treatment retention and increase overdose reversals (through the use of naloxone).

Approximately 2,200 enrollees with newly compliant benefit coverage would use FDA-approved AUD medications, though 50% or more may experience relapse. Health outcomes of successful treatment would

include decreases in undesirable outcomes such as injuries/accidents and poor pregnancy outcomes.

Approximately 5,500 enrollees with newly compliant benefit coverage would use FDA-approved TUD medications, some of whom 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., cancer and heart attacks).

Long-Term Impacts

Long-term utilization of FDA-approved OUD medications could increase as OUD prevalence increases in the state. CHBRP estimates that the level of use per user per year predicted in 2019 (see Table 1) 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 OUD in treatment to remain limited, even as the total number of persons with OUD increases. In the case of AUD and TUD treatment, there is very low baseline utilization of the FDA-approved prescription-only medications for the two conditions. Physicians and patients are not frequently using the prescription-only medications. As the lack of use does not appear to be due to restrictions imposed by health plans and insurers, limited use is expected to continue.

A key barrier to abstinence for any SUD is patient interest and readiness to abstain. CHBRP anticipates the demand for treatment of OUD, AUD, and TUD would continue as relapsed patients attempt abstinence again and first-time initiators join the pool of patients seeking care. SB 11 would continue to facilitate prescription medication treatment for some enrollees (whose insurance did not previously offer compliant benefit coverage), but limited patient readiness for SUD treatment and the demand-supply mismatch for OUD and AUD treatment are likely to remain significant barriers to care in future years assuming no other public policies are implemented.

Although the quantitative long-term impact of SB 11 on premature death associated with OUD, AUD, and TUD is unknown, it stands to reason, based on the effectiveness of FDA-approved medications for these SUDs, that there would be a reduction in premature deaths for those enrollees who successfully engage in treatment.

Essential Health Benefits and the Affordable Care Act

SB 11 would alter the terms and conditions of existing benefit coverage, but would not require coverage for a new benefit and so appears not to exceed the definition of EHBs in California.