Key Findings:

Analysis of California Assembly Bill 2384 Medication-Assisted Treatment

Summary to the 2017–2018 California State Legislature, April 15, 2018

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

The version of California Assembly Bill (AB) 2384 analyzed by CHBRP would require coverage for medication-assisted treatment (MAT) for opioid use disorder (OUD).

1. In 2019, 100% of the 23.4 million Californians enrolled in state-regulated health insurance, will have insurance subject to AB 2384.
2. **Benefit coverage.** AB 2384 would not create new benefit coverage for commercial enrollees, but would prohibit utilization management and limit cost sharing. The bill would create new coverage for Medi-Cal managed care enrollees, similar to what is currently available through Drug Medi-Cal, but without utilization management.
3. **Utilization.** MAT users would increase from 20% to 25% of enrollees with OUD. Use of behavioral therapy and naloxone (anti-overdose medication) would increase for new and continuing MAT users. Naloxone use would shift towards a more expensive option.
4. **Expenditures.** Total net annual expenditures, (reduced by cost offsets) would increase by $24,668,000 (0.0159%).
5. **Medical effectiveness.** There is *clear and convincing evidence* that medications are more effective than a placebo or no treatment for retention of patients in treatment, abstinence from opioids, and a *preponderance of evidence* that receipt of medication reduces mortality.
6. **Public health.** AB 2384 would decrease rates of illicit drug use, opioid overdose, related mortality, poor maternal/fetal outcomes, and HIV and hepatitis C transmission among new MAT users.
7. **Long-term impacts.** Increases in the number of enrollees with OUD could increase health and cost impacts of AB 2384.

CONTEXT

The federal Substance Abuse and Mental Health Services Administration (SAHMSA) defines medication-assisted treatment (MAT) as the use of medications approved by the Food & Drug Administration (FDA), in combination with counseling and behavioral health therapies.[1] AB 2384 specifies medications related to the treatment of opioid use disorder (OUD), which is defined as a pattern of opioid use (e.g., oxycodone, hydrocodone, heroin, etc.) that results in significant impairment, or distress.

A number of structural barriers, including federally limited provider capacity, and attitudinal barriers, including the unwillingness of persons with OUD to seek treatment, dampens utilization of MAT for OUD. Only 11% of persons with OUD seek treatment within a year of onset and only 24% seek treatment within 10 years of onset — and remaining in treatment is a challenge for many who begin it.

Health plans and insurers commonly use a number of utilization management tools to manage costs and to ensure the appropriateness of care. For some enrollees with OUD, some of these tools may create structural barriers to accessing coverage for MAT.

BILL SUMMARY

The structure of AB 2384 is complex and CHBRP has made assumptions to analyze it, focusing on the bill's impacts on benefit coverage related to outpatient MAT for OUD. This analysis focuses on the impacts AB 2384 may have by requiring:

- On-formulary outpatient prescription drug (OPD) benefit coverage for maintenance MAT medications (buprenephrine, combination buprenephrine-naloxone, and extended-release naltrexone) and for emergency (anti-overdose) medications (naloxone);

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

- Medical benefit coverage necessary for some outpatient maintenance drugs (methadone, which is only dispensed by federally certified centers, as well as extended-release naltrexone, buprenorphrine implants, and extended-release buprenorphrine, which requires implantation or injection by a clinician); and
- Mental health benefit coverage for outpatient behavioral therapy.

In addition, for the benefit coverage listed above, this analysis considers impacts of AB 2384's prohibitions related to:

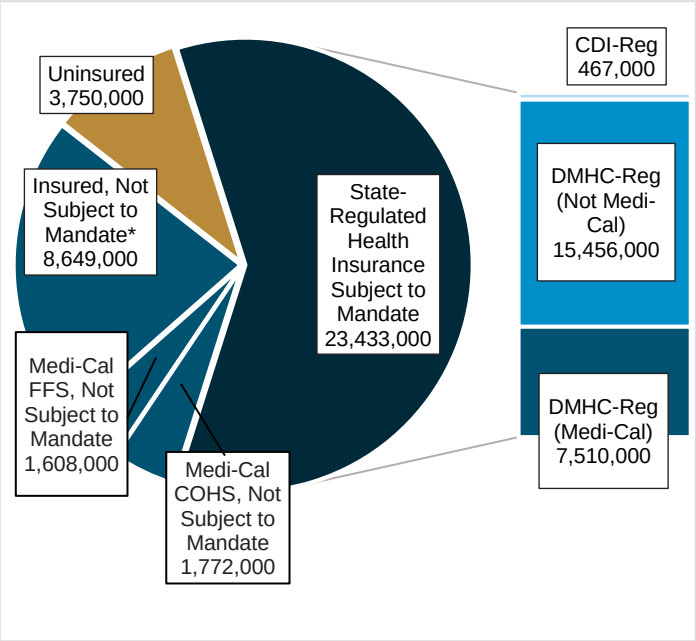
- Medical necessity review;
- Prior authorization requirements;
- Step therapy, fail first, or other protocols that may conflict with a prescribed course of treatment;
- Coverage denials based on prior success or failure with the medication-assisted treatment;
- Limitation of coverage to pre-designated facilities;
- Limits related to number of visits, days of coverage, scope or duration of treatment, or other, similar limits; and
- Annual or lifetime dollar limits or financial requirements different from those relevant to other covered illnesses.

This analysis assumes the utilization management prohibitions listed above would be applicable only to coverage of behavioral therapy and naloxone for enrollees with OUD utilizing a maintenance MAT medication.

PLEASE NOTE: CHBRP does not provide legal interpretation. While the assumptions listed above allowed CHBRP to address key issues and complete its work within the time allotted, regulators and other legal experts may interpret the bill's complex provisions differently. **The cost impacts projected in this report could be exponentially higher** if AB 2384 would (1) require coverage for outpatient treatment of substance use disorders other than opioid addiction, (2) affect coverage of behavioral therapy and/or naloxone that is independent of maintenance MAT medication use, (3) broadly require closed network plans/policies to cover treatments prescribed by or delivered by out-of-network providers/facilities,[2] and/or (4) directly impact coverage of inpatient treatment.

Figure 1 notes how many Californians have health insurance that would be subject to AB 2384.

Figure 1. Health Insurance in CA and AB 2384



Source: CHBRP 2018.
Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

IMPACTS

Medical Effectiveness

There is *clear and convincing evidence* that medications used to provide MAT for OUD are more effective than a placebo or no treatment for retention of patients in treatment, abstinence from opioids, and birth outcomes. There is a *preponderance of evidence* that receipt of medication reduces mortality. Depending on the outcome, there is either *inconclusive* or *insufficient* evidence to determine whether adding a structured behavioral therapy intervention to medication improves outcomes. With the exception of birth outcomes, where there is *limited* evidence that buprenorphine and buprenorphine-naloxone are more effective than methadone, evidence about the relative effectiveness of these medications is *inconclusive*. Persons with OUD have more difficulty initiating treatment with extended-release naltrexone than buprenorphine-naloxone because they must be completely detoxified

[2] For this analysis, CHBRP assumes closed networks would be required to cover outpatient services provided by methadone clinics, but not be required to cover other out-of-network services or providers.

from opioids before beginning treatment, but outcomes of treatment with the two medications are similar for persons who successfully initiate treatment.

There is *insufficient evidence* to assess the impact of utilization management on use of medication to treat OUD and patient outcomes.

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, almost all commercial enrollees have on-formulary OPD coverage for the drugs, medical benefit coverage for the outpatient services, and mental health coverage for the behavioral therapy mentioned in AB 2384. Because such benefits are frequently contractually carved out (covered, instead, through Drug Medi-Cal), few Medi-Cal beneficiaries enrolled in managed care have on-formulary OPD coverage for the drugs, medical benefit coverage for the outpatient services, or mental health coverage for the behavioral therapy mentioned in AB 2384.

At baseline, most enrollees have benefit coverage not subject to medical necessity review or prior authorization for MAT-related drugs or behavioral therapy. However, other forms of utilization management, including in-network restrictions and limits on utilization, are relevant for most enrollees and could impact utilization of MAT to treat OUD.

Postmandate, all enrollees would have benefit coverage fully compliant with AB 2384.

Utilization

CHBRP assumes that the removal of utilization management tools would result in an increase from 20% to 25% of enrollees with OUD utilizing MAT. CHBRP assumes that the remaining structural and attitudinal barriers would dampen use of MAT among the other 75% of enrollees with OUD. For new and continuing users of MAT, CHBRP assumes that the removal of utilization management barriers would increase use of behavioral therapy by 5% and use of naloxone (the anti-overdose medication) by 5%.

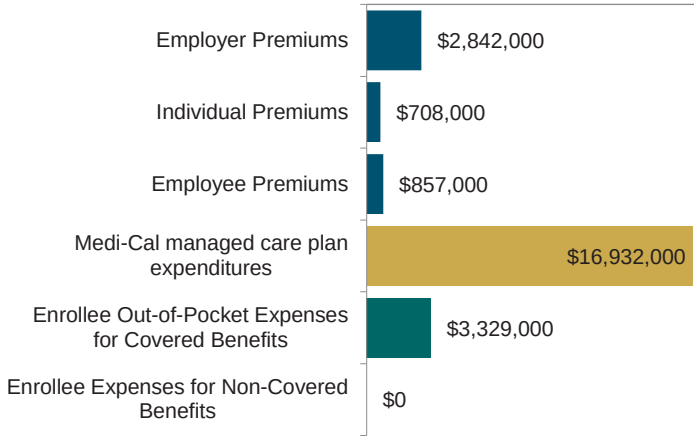
Unit Costs

Although the frequency of services will increase due to new users and removal of utilization management, unit cost of services and MAT maintenance mediations is not anticipated to change, postmandate, However, due to the removal of utilization management related to brand-name drug use, CHBRP assumes that doses of naloxone (the anti-overdose medication) provided to MAT patients will shift to greater use of auto-injectors ($4,603 per unit) and lesser use of pre-filled syringes and nasal spray ($94 per unit), which will raise the average unit cost for naloxone.

Expenditures

As presented in Figure 2, the expected increases in MAT and related services would increase total net annual expenditures for enrollees in DMHC-regulated plans and CDI-regulated policies. The expenditure impacts presented in Figure 2 include expected offsets for the decreased use of some services (such as inpatient days, emergency room visits, and imaging) expected for new users of MAT. Offsets related to commercial enrollees are larger due to the higher prices paid (Medi-cal managed care plans have been generally successful in negotiating or setting lower prices and so would see less of an offset impact on costs), except for services with restrictions or additional licensure requirements on suppliers like methadone and buprenorphine.

Figure 2. Expenditure Impacts of AB 2384 – net change $24,668,000



Source: CHBRP, 2018.

Medi-Cal

Medi-Cal managed care enrollee OUD prevalence and related use of MAT is expected to be roughly twice that of the commercially insured population and so the impacts of AB 2384 are expected to be larger for Medi-Cal.

CHBRP would expect that continuing MAT users would continue to use Drug Medi-Cal coverage, but expects that the prohibition on utilization management among Medi-Cal managed care plans would prompt some additional Medi-Cal enrollees to access MAT using managed care plan benefit coverage.

AB 2384 would increase Medi-Cal's total net annual expenditures for enrollment of beneficiaries in managed care by $16,932,000 or 0.0579%.

CalPERS

AB 2384 would increase CalPERS' total net annual expenditures by $148,000 or 0.0027%, as the offsets applicable for other commercial enrollees newly in MAT for OUD would occur for some CalPERS enrollees as well.

Number of Uninsured in California

No measureable impact is projected.

Public Health

In the first year postmandate, CHBRP projects that AB 2384 would decrease the illicit drug use, opioid overdose, overdose-related mortality, poor maternal/fetal outcomes, and HIV and hepatitis C transmission among the 9,979 new MAT users.

The public health impact of AB 2384 may be less than could be anticipated for several reasons including structural barriers, such as the limited number of providers. Attitudinal barriers also pose significant barriers for some patients. The nature of addiction precludes some people with OUD from recognizing their need for help as well as stigma from family, friends, and employers in acknowledging addiction and from providers recognizing opioid replacement therapy as a valid, effective treatment.

Long-Term Impacts

The opioid epidemic across the U.S. and in California continues to grow, and CHBRP projects that the demand for MAT will continue as relapsed OUD patients attempt MAT again and first-time MAT initiators join the pool of patients seeking care. AB 2384's removal of utilization management tools would continue to facilitate MAT treatment for some number of enrollees. However, CHBRP anticipates that the MAT demand-supply mismatch and limited patient readiness for treatment will remain significant barriers to care.

Essential Health Benefits and the Affordable Care Act

As AB 2384 would alter the terms and conditions of existing benefit coverage but would not require coverage for a new state benefit mandate, the bill appears not to exceed the definition of essential health benefits (EHBs) in California.