California Health Benefits Review Program

Analysis of California Assembly Bill 2384
Medication-Assisted Treatment

A Report to the 2017-2018 California State Legislature April 15, 2018

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

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:

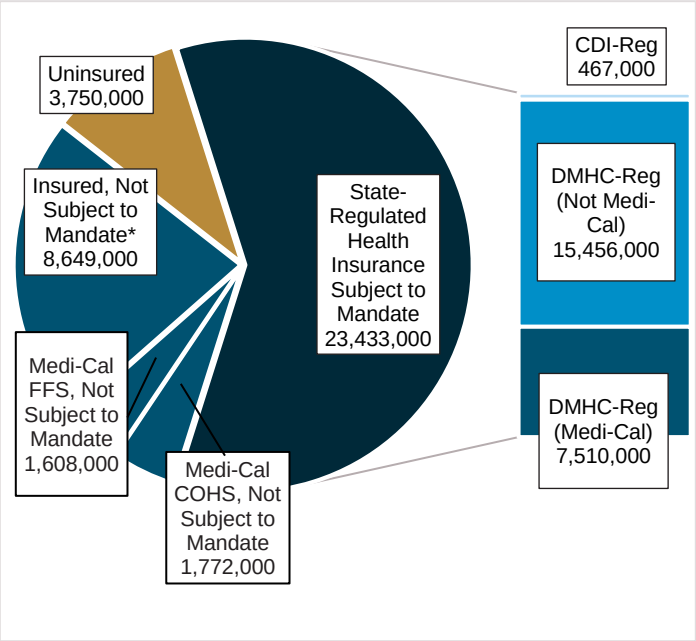
- Medical necessity review;
- Prior authorization requirements;
- Step therapy, fail first, or other protocols that may conflict with a prescribed course of treatment;
- Coverage denials based on prior success or failure with the medication-assisted treatment;
- Limitation of coverage to pre-designated 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%.

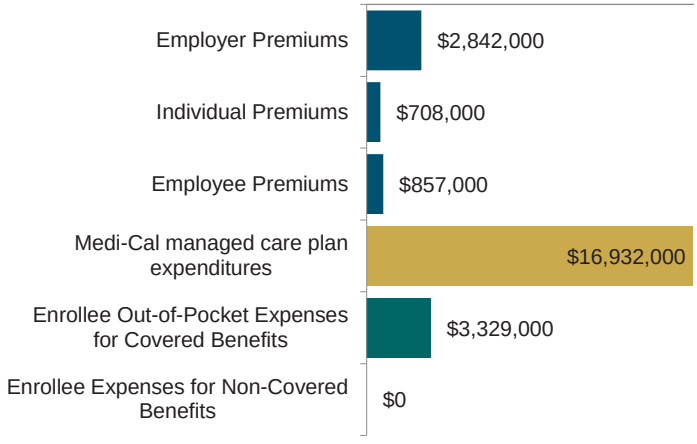
Unit Costs

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.

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April 15, 2018

California Health Benefits Review Program
MC 3116; Berkeley, CA 94720-3116
www.chbrp.org

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.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed 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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Table 1. 2019 Impacts on Benefit Coverage, Utilization, and Cost related to AB 2384

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	23,433,000	23,433,000	0	0%
Total enrollees with health insurance subject to AB 2384	23,433,000	23,433,000	0	0%
Percentage of enrollees with health insurance subject to AB 2384	100%	100%	0%	0%
Total Enrollees with OPD Coverage	22,412,000	22,412,000	0	0%
Number of enrollees with health insurance fully compliant with AB 2384 - Commercial Coverage (f)	1,021,111	14,902,000	13,880,889	1359%
Percentage of enrollees with health insurance fully compliant with AB 2384 — Commercial Coverage (h)	7%	100%	93%	1359%
Number of enrollees with health insurance fully compliant with AB 2384 — Medi-Cal Coverage	N/A	7,510,000	7,510,000	100%
Percentage of enrollees with health insurance fully compliant withAB 2384 — Medi-Cal Coverage	N/A	100%	100%	100%
Number of enrollees with health insurance partially compliant with AB 2384 — Commercial Coverage (g)	13,880,889	0	-13,880,889	-100%
Percentage of enrollees with health insurance partially compliant with AB 2384 — Commercial Coverage	93%	0%	-93%	-100%
Number of enrollees with health insurance partially compliant with AB 2384 — Medi-Cal Coverage	N/A	0	0	100%
Percentage of enrollees with health insurance partially compliant with AB 2384 — Medi-Cal Coverage	N/A	0%	0%	100%
Utilization and unit cost				
Number of Enrollees with OUD using MAT – Commercial and CalPERS				

MAT Drugs				
Methadone	11,696	14,619	2,923	25.0%
Buprenorphine	2,296	2,870	574	25.0%
Combination Buprenorphine / Naloxone	3,467	4,334	867	25.0%
Naltrexone	2,033	2,542	508	25.0%
Total MAT Drugs	19,493	24,365	4,872	25.0%
Naloxone (Overdose Reversal)	1,054	1,317	263	25.0%
Behavioral Therapy	8,867	11,083	2,216	25.0%
Number of Enrollees with OUD using MAT – Coverage through Medi-Cal Managed Care (not Drug Medi-Cal)				
MAT Drugs				
Methadone	0	3,064	3,064	100.0%
Buprenorphine	0	602	602	100.0%
Combination Buprenorphine / Naloxone	0	908	908	100.0%
Naltrexone	0	533	533	100.0%
Total MAT Drugs	0	5,107	5,107	100.0%
Naloxone (Overdose Reversal)	0	276	276	100.0%
Behavioral Therapy	0	2,323	2,323	100.0%
Count of Monthly Scripts (Based on 30-Day Supply) — Commercial and CalPERS				
MAT Drugs				
Methadone (i)	118,642	148,295	29,653	25.0%
Buprenorphine	11,264	14,079	2,815	25.0%
Combination Buprenorphine / Naloxone	20,699	25,872	5,173	25.0%
Naltrexone	5,756	7,195	1,439	25.0%
Naloxone (Overdose Reversal)	1,158	1,519	362	31.2%
Total Number of Visits per Year — Commercial and CalPERS				
Behavioral Therapy	115,200	151,191	35,991	31.2%
Count of Monthly Scripts (Based on 30-Day Supply) — Coverage through Medi-Cal Managed Care (not Drug Medi-Cal)				
MAT Drugs				
Methadone (i)	0	31,082	31,082	100.0%
Buprenorphine	0	2,951	2,951	100.0%
Combination Buprenorphine / Naloxone	0	5,423	5,423	100.0%
Naltrexone	0	1,508	1,508	100.0%
Naloxone (Overdose Reversal)	0	318	318	100.0%

Total Number of Visit per Year — Coverage through Medi-Cal Managed Care (not Drug Medi-Cal)				
Behavioral Therapy	0	33,743	33,743	100.0%
Average Count of Monthly Scripts Supplied per User per Year				
MAT Drugs				
Methadone (i)	10.14	10.14	-	0.0%
Buprenorphine	4.91	4.91	-	0.0%
Combination Buprenorphine / Naloxone	5.97	5.97	-	0.0%
Naltrexone	2.83	2.83	-	0.0%
Naloxone (Overdose Reversal)	1.10	1.15	0.05	5.0%
Average Annual Cost / User — Commercial and CalPers				
MAT Drugs				
Methadone (i)	$5,610	$5,610	$0	0.0%
Buprenorphine	$1,388	$1,388	$0	0.0%
Combination Buprenorphine / Naloxone	$2,239	$2,239	$0	0.0%
Naltrexone	$620	$620	$0	0.0%
Naloxone (Overdose Reversal)	$2,352	$2,743	$391	16.6%
Behavioral Therapy	$2,600	$2,730	$130	5.0%
Average Annual Cost / User) — Coverage through Medi-Cal Managed Care (not Drug Medi-Cal)				
MAT Drugs				
Methadone (i)	$0	$5,610	$5,610	100%
Buprenorphine	$0	$1,388	$1,388	100%
Combination Buprenorphine / Naloxone	$0	$2,018	$2,018	100%
Naltrexone	$0	$558	$558	100%
Naloxone (Overdose Reversal)	$0	$2,469	$2,469	100%
Behavioral Therapy	$0	$1,163	$1,163	100%
Expenditures				
Premium Expenditures by Payer				
Private Employers for group insurance	$69,302,946,000	$69,305,640,000	$2,694,000	0.0039%
CalPERS HMO employer expenditures(c)	$5,383,103,000	$5,383,251,000	$148,000	0.0027%
Medi-Cal Managed Care Plan expenditures(d)(f)	$29,259,588,000	$29,276,520,000	$16,932,000	0.0579%
Enrollees for individually purchased insurance	$15,358,027,000	$15,358,735,000	$708,000	0.0046%
Individually Purchased — Outside Exchange	$6,539,649,000	$6,539,978,000	$329,000	0.0050%

Individually Purchased — Covered California	$8,818,378,000	$8,818,757,000	$379,000	0.0043%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care(a)(b)	$21,267,154,000	$21,268,011,000	$857,000	0.0040%
Enrollee Expenses				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	$14,896,952,000	$14,900,281,000	$3,329,000	0.0223%
Enrollee expenses for noncovered benefits(e)	$0	$0	$0	0.00%
Total Expenditures	$155,467,770,000	$155,492,438,000	$24,668,000	0.0159%

Source: California Health Benefits Review Program, 2018.

Notes: (a) This population includes persons with privately funded (including Covered California) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.
(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees have an OPD benefit not subject to DMHC (see Appendix Z), so 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) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal managed care.

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

(e) Although enrollees with newly compliant benefit coverage may have paid for some treatments or prescription drugs before AB 2384, CHBRP cannot estimate the frequency with which such situations may have occurred and therefore cannot estimate the related expense. Postmandate, such expenses would be eliminated, though enrollees with newly compliant benefit coverage might, postmandate, pay for some treatments or prescription drugs for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.
(f) Fully compliant plans in this table do not have an OPD benefit, the 93% of plans that are not fully compliant with AB 2384 are those with OPD benefits, none of which cover all of the MAT drugs and services without any utilization management as required by AB 2384

(g) Information on partially compliant plans can be found in Table 4-6, which show the types of MAT drugs and services covered by each plan and the types of utilization management used in each plan. All of the plans regulated by AB 2384 used utilization management tools for MAT drugs and services.

(h) At baseline, the enrollees reported with fully compliant health insurance have no OPD benefit regulated by DMHC or CDI (see Appendix D). AB 2384 requires changes to health insurance that includes an OPD benefit.

(i) Methadone as a treatment for OUD is only available from and is dispensed to many patients only at federally certified methadone clinics. For ease of readability, methadone use is characterized (as are the other drugs in this anlaysis) in terms of scripts, though much utilization of methadone would occur through enrollee's visits to methadone clinics.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; OPD = outpatient prescription drug; OUD = opioid use disorder.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[3] conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2384, Medication-Assisted Treatment.

Bill Language and Key Analytic Assumptions

The language 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 medication-assisted treatment (MAT) for opioid use disorder (OUD).

For treatment of opioid addiction, AB 2384 would require on-formulary outpatient prescription drug (OPD) benefit coverage of medications containing any or all of the following drugs, all of which are used to treat OUD:

- Maintenance medications (for continuous use) including:
  - Buprenorphine
  - Combination buprenorphine-naloxone
  - Extended-release naltrexone
- Emergency medications (for opioid overdoses) including:
  - Naloxone

Although the bill specifies on-formulary OPD benefit coverage, CHBRP has assumed AB 2384 would require medical benefit coverage of outpatient services related to (1) methadone, which cannot be covered through an OPD benefit,[4] as well as (2) extended-release naltrexone, buprenorphine implants, and extended-release buprenorphine, all of which require outpatient clinical services for injection or implantation.[5] Both of these medications are maintenance medications for OUD treatment. Considering the list of medications specified in the bill — a set relevant to treatment of OUD — CHBRP has focused on the impacts AB 2384 would have on benefit coverage related to OUD treatment.

Because the bill defines MAT as inclusive of behavioral therapy and includes a definition of behavioral therapy, CHBRP has assumed AB 2384 would require mental health benefit coverage of outpatient behavioral therapy when provided in conjunction with a maintenance medication used to treat OUD. Although the definition provided by AB 2384 for MAT does not exclude related inpatient services, CHBRP has focused on the impacts AB 2384 would have on benefit coverage related to outpatient treatments.

CHBRP has assumed that AB 2384 would not apply to the health insurance of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI) that do not include an OPD benefit (see Table 1). As noted in

[3] CHBRP's authorizing statute is available at http://chbrp.org/faqs.php.
[4] 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)
[5] Involving provider services to inject, extended-release naltrexone may be completely covered through a medical benefit during an outpatient visit or may also involve an OPD benefit (for the medication itself).

Appendix D, less than 5% of enrollees in plans and policies regulated by DMHC or CDI have no OPD benefit through their state-regulated health insurance.

For the medications used in treating OUD that are covered, on formulary, through an OPD benefit, AB 2384 would prohibit:

- 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.

Having assumed medical benefit coverage would be required for outpatient services related to methadone and extended-release naltrexone, and that mental health benefit coverage would be required for behavioral therapy provided in conjunction with a medication treating OUD, CHBRP has also assumed that the prohibitions listed above would be applicable only to the benefit coverage of enrollees with OUD utilizing a maintenance MAT medication.

Although naloxone may be prescribed for any person using opioids, CHBRP has assumed that the prohibitions listed above would be applicable only to the benefit coverage of enrollees with OUD utilizing a maintenance MAT medication.

Although AB 2384 would prohibit limiting coverage to predesignated facilities, CHBRP has assumed AB 2384 would not generally require closed network plans or policies to cover tests, treatments, or services delivered through any licensed facility or generally require closed network plans or policies to allow prescriptions to be filled at any pharmacy. CHBRP has assumed that all plans and policies would have to include federally designated methadone clinics in their networks, as methadone for treatment of OUD is only available at these facilities.

Although AB 2384 defines medical necessity as being "determined by a licensed health care professional in consultation with the patient," CHBRP has assumed AB 2384 would not generally require closed network plans or policies to cover tests, treatments, or services prescribed or ordered by any licensed provider.

Further descriptions of the utilization management techniques that AB 2384 would prohibit are included in the *Background* section of this report.

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,[6] and/or (4) directly impact coverage of inpatient treatment.

The full text of AB 2384 can be found in Appendix A.

Relevant Populations

All health plans and policies regulated by DMHC or CDI would be subject to AB 2384, but the bill would require change for the health insurance of the 22.4 million enrollees with OPD coverage (57% of all Californians). This represents 95% of the 23.4 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — plans and policies regulated by DMHC or CDI.

Interaction with Existing Requirements

Although a number of federal laws and regulations restrict providers in regards to the medications specified by AB 2384 (see the *Background* section of this report), CHBRP is aware of few state or federal benefit coverage mandates or provisions that would directly interact with compliance to the outpatient OUD coverage requirements addressed in AB 2384.

California Policy Landscape

California law and regulations

CHBRP is unaware of California laws or regulations that directly address coverage of outpatient mediations or therapy as treatments for OUD.

CHBRP is aware that the California Department of Health Care Services (DHCS) regularly excludes coverage for substance use disorder (SUD) treatment in contracts with DMHC-regulated plans. When such “carve outs” are in effect, SUD treatments are covered for Medi-Cal beneficiaries by Drug Medi-Cal.

Similar requirements in other states

CHBRP is unaware of benefit coverage legislation in other states similarly addressing coverage for the medications and behavioral therapy used in the outpatient treatment of OUD.

Federal Policy Landscape

Federal Mental Health Parity and Addiction Equity Act

The federal Mental Health Parity and Addiction Equity Act (MHPAEA) addresses parity for mental health benefits.[7] The MHPAEA requires that if mental health or substance use disorder services are covered,

[6] 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.
[7] Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the ACA.

cost-sharing terms and treatment limits be no more restrictive than the predominant terms or limits applied to medical/surgical benefits. The MHPAEA applies to the large-group market, but the ACA requires small-group and individual market plans and policies purchased through a state health insurance marketplace to comply with the MHPAEA. This federal requirement is similar to the California mental health parity law,[8] although the state law applies to some plans and policies not captured in the MHPAEA.

For this analysis, CHBRP presumes that compliance with MHPAEA and/or the California mental health parity law would be similar to compliance with the requirements AB 2384 would make regarding financial aspects of the addressed covered benefits.

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 2384 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[9]

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[10,11]

States may require QHPs to offer benefits that exceed EHBs.[12] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.[13,14] State rules related to provider types, cost-sharing, or

[8] H&SC Section 1374.72; IC Section 10144.5 and 10123.15.
[9] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.
[10] The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.
[11] H&SC Section 1367.005; IC Section 10112.27.
[12] ACA Section 1311(d)(3).
[13] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov\fdsys\pkg\FR-2013-02-25\pdf\2013-04084.pdf.
[14] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.[15]

AB 2384, would alter the terms and conditions of existing benefit coverage, but would not require coverage for a new state benefit mandate and so appears not to exceed the definition of EHBs in California.

[15] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

BACKGROUND ON MEDICATION-ASSISTED TREATMENT FOR SUBSTANCE USE DISORDERS

AB 2384 would require coverage for medication-assisted treatment (MAT) for substance use disorders (SUD) with a particular emphasis on treatment for opioid use disorder (OUD). SUD is clinical diagnosis for addiction that meets the following *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)* characteristics: impaired control, social impairment, risky use, increased tolerance, and withdrawal symptoms (APA, 2013). The American Society of Addiction Medicine characterizes addiction as "the inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission" (ASAM, 2011).

What Is MAT?

The federal Substance Abuse and Mental Health Services Administration (SAMHSA) defines MAT as "the use of FDA-approved medications, in combination with counseling and behavioral health therapies to provide a 'whole person' approach to the treatment of substance abuse disorders" (SAMHSA, 2018). MAT uses one or more of the following treatment methods, concurrently or consecutively, based on clinician recommendation: medication, individual and group counseling, and/or other behavioral therapies in outpatient or inpatient/residential settings (SAMHSA, 2015). In general, FDA-approved medications are used for long-term maintenance treatment of SUD to either reduce cravings, produce unpleasant effects when combined with substance, or block the euphoric effect of substances. Behavioral therapies modify behavior, improve life skills and self-efficacy, and provide awareness of triggers that promote relapse (NIDA, 2018). See the *Medical Effectiveness* section for a full description and evaluation of relevant medications and behavioral therapies.

Description and Prevalence of Opioid Use Disorder in California

AB 2384 specifies medications related to the treatment of OUD. The DSM-5 characterizes OUD as a pattern of opioid use (e.g., oxycodone, hydrocodone, and heroin) that results in significant impairment or distress. People meeting at least two of 11 specified criteria within a 12-month period are diagnosed with mild, moderate, or severe OUD depending on the number of criteria met (APA, 2013).

The estimated prevalence rate of OUD in the U.S. is 0.891% (Jones, 2015). CHBRP calculated that the prevalence rate is approximately twice as high in the Medicaid population (1.36%) as compared with the commercial population (0.654%) based on data from the Medicaid and CHIP Payment and Access Commission (MACPAC, 2017).

Two consequences of OUD are increased risk of mortality and increased use of health services due to overdose. The California Opioid Overdose Surveillance Dashboard[16] presented an *age-adjusted mortality*

[16] The California Opioid Overdose Surveillance Dashboard, a collaboration between the California Department of Public Health, Office of Statewide Health Planning and Development, Department of Justice, and the California Health Care Foundation, integrates statewide and geographically specific non-fatal and fatal opioid-involved overdose and opioid prescription data to surveil several short and long-term goals by California's Prescription Drug Overdose Prevention program. Data are harvested from the Multiple Cause of Death File (CDPH Vital Statistics); Emergency Department Visit & Inpatient Discharge Data (OSHPD); and Controlled Substance Utilization Review and Evaluation System (CURES). Available at: https://pdop.shinyapps.io/ODdash_v1/

rate for opioid overdose deaths of 4.9/100,000 Californians in 2016 (2,031 deaths) (CDPH, 2018). Table 2 shows that the rates of mortality associated with OUD generally remained constant between 2010 and 2016 (most recent data year). However, there are significant rate differences among demographic groups. Native Americans, followed by whites, had the highest opioid mortality rates in California in 2016 (12.8/100,000 and 8.4/100,000) (CDPH, 2018) as compared with Asians who had the lowest opioid overdose mortality rate at 0.7/100,000. California males were twice as likely to die from opioid overdose as females. Between 2010 and 2016, emergency department (ED) use increased significantly for opioid (excluding heroin) overdose, and most notably for heroin-only overdose. Males and females experienced more than a two-fold increase in heroin-only ED visits between 2010 and 2016.

In addition to greater risk of mortality, patients with prescription OUD are at a higher risk for developing cardiac dysrhythmias, respiratory depression, impairment in daily function, and premature death (Blanco et al., 2013) as well as HIV, hepatitis A, B, and C, tuberculosis, and endocarditis (SAMHSA, 2016; Tsui et al., 2014).

Table 2. Changes Between 2010 and 2016 in California Opioid-related Mortality Rates and Related Healthcare Use

	Age-adjusted rate per 100,000	# of deaths	Age-adjusted rate per 100,000	# of deaths
Opioid-related Mortality (a)				
	2016		**2010**	
California	4.9	2,031	4.9	1,909
Male	6.7	1,381	6.3	1,209
Female	3.0	650	3.6	700
White	8.4	1,420	8.5	1,432
Black	5.2	138	5.1	129
Latino	2.7	398	2.4	300
Native Americans	12.8	27	9.4	19
Asian	0.7	48	0.5	29
Overdose-related Emergency Department Visits (b)				
	2016		**2010**	
California: Opioid (excl. heroin)	11.2	4,623	9.4	3,594
California: Heroin only	8.8	3,630	3.4	1,298
Male (opioid excl. heroin)	11.0	2,249	9.6	1,776
Male (heroin only)	13.3	2,775	5.4	1,001
Female (opioid excl. heroin)	11.5	2,374	9.7	1,818

	Age-adjusted rate per 100,000	# of deaths	Age-adjusted rate per 100,000	# of deaths
Female (heroin only)	4.2	855	1.58	297

Source: California Health Benefits Review Program, 2018. Based on data from the California Opioid Overdose Surveillance Dashboard (CDPH, 2018).

Notes: (a) Opioid-related mortality defined as acute poisoning deaths involving opioids such as prescription opioid pain relievers (i.e., hydrocodone, oxycodone, and morphine), heroin, and opium. Death related to chronic use of drugs excluded from this indicator. (b) Overdose-related emergency department visits defined as emergency department visits caused by non-fatal acute poisonings due to the effects of all opioids drugs, excluding heroin, regardless of intent (e.g., suicide, unintentional, or undetermined). Emergency department visits related to late effects, adverse effects, and chronic poisonings due to the effects of drugs (e.g., damage to organs from long-term drug use) are excluded from this indicator.

Medications Used in MAT for Opioid Use Disorder

FDA-approved medications for OUD MAT are buprenorphine and methadone. Also known as opioid agonist treatment, these opioids are administered under physician care to control cravings (see *Potential Barriers to MAT* in this section for descriptions of provider restrictions in prescribing methadone and buprenorphine) (Connery, 2015). Two other FDA-approved prescription drugs used to treat OUD are opioid-antagonists: Naloxone,[17] which can be used in combination with buprenorphine (Suboxone®) and naltrexone, an extended-release non-opioid drug that blocks the effect of opioids (SAMHSA, 2016). See the *Medical Effectiveness* section for detailed discussion of these medications.

Uptake Rate of MAT for Opioid Use Disorder

Blanco et al. (2013) estimated that the lifetime probability of patients seeking treatment for prescription opioid use disorder is approximately 40%, with 11% of people with OUD seeking treatment within the first year after onset of the disorder and 24% seeking treatment within 10 years after onset.

Structural and Attitudinal Barriers to MAT

Although insurance coverage and utilization management may provide some barrier to treatment, provider supply and geographic access are significant structural barriers in California. For many with OUD, attitudinal barriers are the most significant barrier to MAT initiation and persistence (Blanco et al., 2013).

Structural: Utilization Management

There are several utilization management tools that insurance carriers use to manage costs and to ensure patients receive appropriate treatment (i.e., preventing drug-drug interactions or clinical contraindications). Insurance carriers' most basic cost and quality control method revolves around medical necessity, which is commonly defined as, "health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." (CMS, 2018). Insurance carriers are permitted to deny coverage for treatments or services not

[17] Naloxone administered alone is a "rescue drug" that is used in emergencies to reverse opioid overdose.

considered medically necessary (or experimental). However, California state law permits enrollees with coverage from plans or policies regulated by DMHC or CDI to appeal denials to the regulatory agency through an Independent Medical Review process (Medi-Cal has a similar process for beneficiaries). See the *Benefit Coverage, Utilization, and Cost Impacts* section for bill-specific discussion about utilization management for OUD.

Prior authorization

Also known as pre-approval or preauthorization, this tool requires providers to obtain insurer approval of treatment or medication before it is covered. In addition to managing costs, prior authorization restrictions can be used to protect enrollees from outdated or potentially dangerous drugs (based on reviews of drug efficacy or severity of side effects) (Curtiss, 2005; Ovsag et al., 2008). Other patient protections associated with prior authorization include limiting quantities/doses of medications (i.e., those with potential for abuse) and medication reviews for drug-drug or drug-disease interactions (i.e., to prevent harmful effects if combined with other drugs or interactions with comorbid conditions) (Curtiss, 2005). Medi-Cal refers to this tool as a "Treatment Authorization Request" (TAR) and removed the TAR requirement for some forms of buprenorphine in 2016 (Joshi et al., 2017).

Step therapy/fail first

A patient is required by the insurance carrier to try and "fail" on alternative drug(s) before the insurer will cover the provider's initial prescription. In many instances, the first step of a step therapy requirement mandates the use of a generic drug before "stepping up" to a more costly drug (PBMI, 2015). In addition to managing the cost of more expensive drugs, step therapy is also used to promote physician and patient compliance with recommended treatment and drug safety guidelines. Step therapy requirements usually recommend starting with a drug that is less expensive and/or has more "post-marketing safety experience" (PBMI, 2015). Additionally, step therapy sometimes requires starting with a less potent drug or dosage, perhaps with fewer side effects, and graduating to more potent drugs as necessary, such as requiring the patient to use prescription Motrin (ibuprofen) for pain management before covering OxyContin (oxycodone), which has potential for misuse or abuse (Curtiss, 2005).

A 2016 survey by the California Society of Addiction Medicine reported that, of the 88 physician respondents, 56% reported difficulty accessing MAT for their insured patients and 46% reported barriers to MAT, such as dose limits (35%), additional written justification required (69%), and "try/fail first" criteria (38%) imposed by insurance carriers (Kan, 2016).

Structural: MAT Provider Restrictions and Supply

Nationally and in California there appears to be a shortage of MAT providers (Knudsen et al., 2017; Stein et al., 2015; Thomas et al., 2017). Federal law restricts methadone treatment to federally-certified opioid treatment programs, known as methadone clinics. Federal law also requires health care providers to receive special training and certification in order to prescribe buprenorphine. The standards are less stringent for naltrexone, which can be prescribed by anyone with prescription-drug prescribing authority.[18]

[18] In addition to covering MAT medications, AB 2384 also specifies coverage for the opioid overdose "rescue drug," naloxone. California recently granted pharmacists the ability to dispense naloxone without a prescription in an effort to prevent opioid overdoses and reduce barriers to immediate care. California Business and Professions code 4052.01.

Methadone providers

Methadone must be initiated through admission to a certified methadone clinic. Initially, patients must take their daily methadone treatment under direct clinical supervision. Once a patient is stabilized, it is possible for some patients to take methadone at home in between required clinic visits. Federal guidelines recommend a minimum 12-month treatment plan, and many patients continue with methadone for years (SAMHSA, 2015). Clemans-Cope et al. (2018) reported that there are 152 SAMHSA-certified methadone clinics in California, which can treat 46,430 patients simultaneously.

Buprenorphine providers

Not all licensed providers may prescribe buprenorphine. Only after completing the federally approved buprenorphine training may providers qualify to for a certificate of waiver to prescribe buprenorphine for the treatment of OUD. The certification requires that providers must be capable of referring patients for counseling and must agree to treat no more than 30 patients in the first year of the waiver. Physicians who wish to increase their patient load to 100 patients after the first year must reapply. Addiction medicine specialist physicians may treat up to 275 patients at a time (SAMHSA, 2018). As of 2017, federal law allows physician assistants and nurse practitioners to apply for a waiver to treat up to 30 patients after completing 24 hours of specified training. Clemans-Cope et al. (2018) estimate that there are 3,813 California providers with waivers for 30 patients, 738 providers with waivers for 100 patients, and 172 providers with 275-patient waivers.

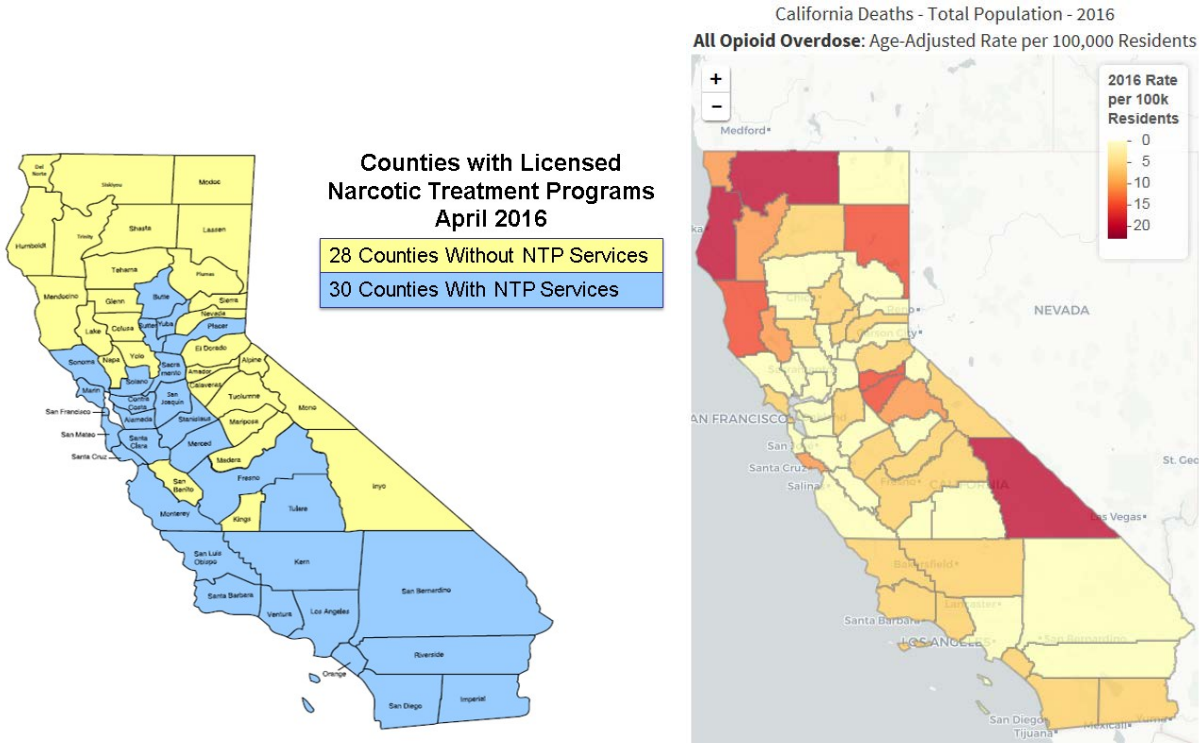
Mismatch in Supply of and Demand for Buprenorphine and Methadone Providers in California

A recent analysis by the Urban Institute estimates that there is gap between the demand for and supply of buprenorphine and methadone providers in California. In their analysis, Clemans-Cope et al. (2018) estimated that 348,193 Californians with OUD are clinically eligible for MAT. However, the authors estimated an additional 3,500 to 4,100 providers would need to be trained and certified to treat this population.[19] A 2016 survey of California physicians (88 respondents representing an 11% response rate) reported that 60% had difficulty referring patients to methadone clinics due to a lack of qualified providers (Kan, 2016). Of survey respondents, 66% also reported patient difficulty with accessing naloxone rescue kits; reasons included insurance barriers, high cost, and lack of accessibility at pharmacies. As is true for many health care services, accessing MAT providers is more difficult in rural areas than in urban areas (Clemans-Cope et al., 2018).

The supply-demand mismatch is apparent by geographic location. Figure 1 shows the distinct mismatch between providers and opioid overdose deaths among rural California counties with many rural areas experiencing the highest rates of opioid death in the state and lowest access to MAT providers (Joshi, et al., 2016).

[19] Unpublished data; Author communication March 2, 2018.

Figure 1. Comparison of counties with narcotic treatment programs and county opioid deaths, 2016



Source: Maps from Joshi et al., 2017 and the California Opioid Overdose Surveillance Dashboard, 2018.

The demand-supply mismatch of MAT providers in California is not unique. To address the national opioid epidemic, the federal government funds a program called Providers Clinical Support System that educates and trains health care professionals in the prevention and treatment of OUD and treatment of chronic pain. It also houses a pilot program that provides technical assistance to providers interested in establishing or expanding evidence-based SUD treatment, including MAT for OUD (PCSS, 2018). In addition, California has developed a strategic plan to target the opioid crisis, which includes provider training (Joshi et al., 2017).

Attitudinal Barriers

The stigma of addiction and the ability to acknowledge an addiction affects patient desire to seek care; even more so for those who have co-occurring psychiatric problems (Fisher et al., 2016; Jones et al., 2015; Verissimo and Grella, 2017). Many people with OUD believe they can solve the problem themselves (Rapp et al., 2006). Rapp et al. (2006) tested a Barrier to Treatment Inventory tool to assess barriers to treatment from the substance abusers' perspective. The researchers validated the tool and reported significant correlation among six of the seven barrier factors (absence of a problem; negative social support; fear of treatment; privacy concerns; time conflict; poor treatment availability; and admission difficulty) suggesting that policies and programs should be designed to address concurrent barriers for individuals.

Additionally, stigma on behalf of providers and families accepting opioid replacement therapy as a valid, effective treatment also remains a barrier (Jones et al., 2015). Certified MAT providers cite concerns about medication diversion, need for structural supports (access to addiction experts, institutional or office support, etc.), and low confidence in treating addiction (Thomas et al., 2017). Several studies suggest

that, of certified buprenorphine providers, only 44% to 66% actually prescribe the drug; and most do not reach their maximum-allowed patient caseload (Jones et al., 2015; Hutchinson et al., 2014; Walley et al., 2008). This leads to wait lists, which have been shown to decrease uptake of MAT by people with OUD (Fisher et al., 2017).

Drug Medi-Cal Organized Delivery System

Medi-Cal beneficiaries obtain SUD treatment from the same certified MAT providers as enrollees in the commercial market; however, the payment and approval structures are different. Since 2012, Medi-Cal beneficiaries have used Drug Medi-Cal to obtain approval and payment for substance use treatment (DHCS, 2012). Responsibility for payment of substance use treatment is carved out of Medi-Cal managed care plan contracts, meaning that the plans are not responsible for covering the cost of MAT (DHCS, 2018). Instead, MAT providers directly bill the state for reimbursement through Medi-Cal fee-for-service.

To improve service delivery to beneficiaries with SUD, Medi-Cal obtained a CMS waiver in 2015 to reorganize the delivery of MAT through the Drug Medi-Cal-Organized Delivery System. Ten counties have executed contracts with the state (37 are pending) to implement a continuum of care modeled on the American Society of Addiction Medicine's recommended SUD treatment protocol (DHCS, 2018). The waiver enables "more local control, accountability, greater administrative oversight, and utilization controls to improve care and efficient use of resources, and coordinate with other systems of care…to enable beneficiaries to achieve sustainable recovery." (DHCS, 2018).

Disparities[20] and Social Determinants of Health[21] Related to MAT and Opioid Use Disorder

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to SUD. See the *Public Health Impacts* section for a full discussion.

[20] 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.

[21] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP's SDoH white paper for further information: http://www.chbrp.org/analysis_methodology/docs/Incorporating Relevant Social Determinants of Health in CHBRP Analyses Final to WEBSITE 033016.pdf.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 2384 would require coverage for medication-assisted treatment (MAT) for opioid use disorder (OUD). Additional information on OUD is included in the *Background on Medication-Assisted Treatment for Substance Abuse Disorders* section. The medical effectiveness review summarizes findings from evidence[22] on MAT, which includes medications alone or plus behavioral therapy. The evidence presented in this section summarizes the literature on MAT from 2007 to present.

As discussed in the *Background on Medication-Assisted Treatment for Substance Abuse Disorders* section, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) defines MAT as "the use of FDA-approved medications, in combination with counseling and behavioral health therapies to provide a 'whole person' approach to the treatment of substance abuse disorders" (SAMHSA, 2018). These treatments may be provided concurrently or consecutively.

OUD encompasses abuse of short-acting opioids, such as heroin and morphine, and semi-synthetic opioids such as oxycodone and hydrocodone. AB 2384 lists five specific medications used for OUD:

- Buprenorphine;
- Methadone;
- Naloxone;
- Extended-release injectable naltrexone; and
- A combination of buprenorphine and naloxone.

Four of these medications — buprenorphine, methadone, extended-released injectable naltrexone, and buprenorphine-naloxone combination are used for maintenance MAT treatment for OUD.

Naloxone is a fast-acting injectable drug that is administered in emergencies to reverse opioid overdose. It is not used as a maintenance treatment for OUD except when combined with buprenorphine.

Methadone is administered in the form of a pill, liquid, or wafer and can only be dispensed only through a federally designated methadone clinic. The extended-release injectable form of naltrexone is administered by physicians in their offices.[23] Buprenorphine and buprenorphine-naloxone combination are administered as a buccal film or a sublingual tablets. Buprenorphine is also available in implantable and injectable formulations that are administered by a physician. Health professionals with prescribing authority who wish to prescribe buprenorphine must complete training and receive a waiver from the federal government to prescribe the drug. Please see the *Background* section for additional information about requirements for dispensing methadone and buprenorphine. Buprenorphine is also formulated as a

[22] Much of the discussion below is focused on reviews of available literature. However, as noted in the medical effectiveness approach document ((http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php; see p.8), in the absence of "fully applicable to the analysis" peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

[23] On December 19, 2017, BioCorRx, Inc., submitted a pre-Investigational New Drug application to the FDA for an implantable formulation of naltrexone. At a meeting on February 12, 2018, the FDA agreed to allow the company to pursue an abbreviated process for obtaining approval for its implants. https://www.biocorrx.com/news-media/press-releases/detail/116/biocorrx-announces-results-of-pre-ind-meeting-with-fda-for

transdermal patch and intravenous solution, but these forms of buprenorphine *are not* approved for treatment of OUD. Persons may take buprenorphine, methadone, and naltrexone medications for months or years to prevent relapse (SAMHSA, 2018).

Multiple forms of behavioral therapy are provided as part of MAT for OUD, including individual and group counseling. Specific types of therapy provided include cognitive behavioral therapy, contingency management, motivational enhancement therapy, and facilitation of participation in 12-step programs. (SAMHSA 2016).

Research Approach and Methods

Studies of MAT for OUD were identified through searches of PubMed, the Cochrane Library, EMBASE, Scopus, and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Care Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English, from 2007 to present. Of the 1,262 articles found in the literature review, 45 were reviewed for potential inclusion in this report on AB 2384, and a total of 28 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not address MAT for OUD, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature. Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Medications used for long-term, maintenance treatment of OUD are also used on a short-term basis to manage symptoms of withdrawal from opioids. CHBRP did not review literature on the effectiveness of these medications for withdrawal management because AB 2384 refers to their use for MAT, which is defined as long-term maintenance treatment to prevent relapse.

CHBRP also did not review literature on the effectiveness of transdermal and intravenous formulations of buprenorphine because the FDA has only approved these formulations of buprenorphine for the treatment of chronic pain.

Key Questions

CHBRP's medical effectiveness review addressed the following questions:

1. What is the effectiveness of medication for maintenance MAT treatment of OUD compared to no treatment or a placebo?

2. Does the combination of medication and behavioral therapy improve outcomes for persons treated for OUD relative to either medication or behavioral therapy alone?

3. What is the relative effectiveness of medications used for maintenance MAT treatment of OUD?

4. What are the harms associated with maintenance MAT medications for treatment of OUD?

5. How does health plans' use of utilization management techniques affect use of maintenance MAT medications for OUD and health outcomes for persons with OUD?

Methodological Considerations

The systematic reviews CHBRP cited included overlapping groups of studies of maintenance MAT medications for OUD. Thus, their conclusions of these systematic reviews regarding the effectiveness of these medications are not independent of one another.

The systematic reviews included randomized controlled trials (RCTs) and observational studies. This research design maximizes ability to discern whether any differences observed between intervention and comparison groups are due to the intervention or to other factors. However, in the case of maintenance MAT medications for OUD, many of the RCTs follow subjects for less than one year, which limits ability to assess the long-term impact of receiving maintenance MAT medications. Most studies that have assessed long-term impacts, such as mortality and transmission of human immunodeficiency virus (HIV) and hepatitis C, are observational studies. Findings from observational studies need to be interpreted with more caution because observational studies are less able to control for other differences between intervention and comparison groups that may affect the outcome of interest.

Outcomes Assessed

Studies of maintenance MAT medications used to treat OUD have primarily examined outcomes related to opioid use and participation in treatment. Outcomes assessed include use of opioids during treatment, use of opioids at follow up, and retention in treatment. Some studies have examined effects of OUD medications on morbidity or mortality. Studies of effects on morbidity have addressed birth outcomes for pregnant women treated for OUD and effects on the likelihood of contracting HIV and hepatitis C, two contagious diseases for which persons who inject opioids are at elevated risk.

Study Findings

Research has demonstrated the effectiveness of maintenance MAT medications for OUD relative to a placebo or no treatment. Most studies were conducted in adults. There is far less literature on effects in adolescents (Minozzi, 2014).

Medication Versus Placebo or No Medication

Methadone

Two systematic reviews of overlapping groups of studies have compared methadone maintenance treatment to a placebo or no treatment for OUD (Fullerton et al., 2014; Mattick, 2009). Both systematic reviews concluded that methadone is more effective than a placebo or no treatment for retaining patients in treatment and reducing use of illegal opioids as measured by self-report and urine/hair analysis. Mattick (2009) assessed 11 RCTs (sample sizes: 32-382 subjects) and found methadone was statistically significantly more effective in retaining patients in treatment and in the suppression of heroin use as measured by self-report and urine/hair analysis (risk ratio (RR)=0.66; 95% confidence interval (CI): 0.56 to 0.78),

Fullerton (2014) included 7 RCTs, 2 quasi-experimental studies (sample sizes: 81-319 subjects) and 15 reviews or meta-analyses of multiple studies. Fullerton et al.'s systematic review (2014) found two systematic reviews and one RCT that addressed the impact of methadone on HIV risk. The authors concluded that receipt of methadone maintenance treatment was associated with lower risk of injecting opioids and engaging in sexual behaviors that elevate a person's risk of contracting HIV. A systematic review of nine studies (with a sample that included 819 incident HIV infections over 23,608 person years of follow-up) concluded that receipt of methadone maintenance treatment reduces risk of HIV transmission (MacArthur, 2012) (rate ratio=0.46; 95% CI: 0.32 to 0.67; P<0.001).

The authors of one systematic review of RCTs found no statistically significant difference in mortality between persons receiving methadone maintenance treatment and persons who received a placebo or no treatment (4 studies; RR=0.48; 95% CI: 0.10 to 2.39) (Mattick, 2009). In a subsequent systematic review of 18 prospective or retrospective cohort studies (sample sizes: 56-122,885 subjects) that had longer follow-up periods than the studies included in Mattick's (2009) systematic review, Sordo (2017) found methadone maintenance treatment is associated with substantial reductions in the risk for all cause and overdose mortality in people dependent on opioids. In patients using methadone maintenance treatment there are, on average, 25 fewer deaths/1000 person years than in patients who do not receive methadone maintenance treatment.

Buprenorphine or buprenorphine-naloxone combination

Mattick et al.'s (2014) Cochrane review of 11 RCTs (sample sizes: 40-736 subjects) found that persons who were given buprenorphine or buprenorphine-naloxone combination medication for maintenance treatment of OUD were more likely to be retained in treatment than people who received a placebo at low (2-6 mg, 5 studies, 1131 participants, RR=1.50; 95% CI: 1.19 to 1.88), medium (7-15 mg, 4 studies; 887 participants; RR=1.74; 95% CI: 1.06 to 2.87), and high doses (≥16 mg, 5 studies; 1001 participants; RR=1.82; 95% CI: 1.15 to 2.90). The authors found that only high-dose buprenorphine (≥ 16 mg) was more effective than placebo in suppressing illicit opioid use measured by urinalysis in the trials (Mattick et al., 2014) (3 studies; 729 participants; standardized mean difference (SMD) -1.17; 95% CI: 1.85 to -0.49).

Two other systematic reviews also found that persons who received buprenorphine or buprenorphine-naloxone were more likely to be retained in treatment than people who received a placebo (Thomas, 2014; Timko, 2016). Thomas et al.'s (2014) systematic review included 17 RCTs, a randomized crossover study, a study using a self-administered survey, a retrospective descriptive study, and seven reviews or meta-analyses (sample sizes: 12-4,497 subjects). Timko et al.'s (2016) review of buprenorphine or buprenorphine-naloxone combination included 14 randomized control trials, four quasi-experimental design studies, and nine cohort studies (sample sizes: 70-1,269 subjects).

In a systematic review of three prospective or retrospective cohort studies (sample sizes: 1373-11,940 subjects) in people with OUD, Sordo (2017) found buprenorphine treatment is associated with substantial reductions in the risk for all cause and overdose mortality in people dependent on opioids relative to not receiving treatment.

One systematic review examining 16 RCTs (sample sizes: 12-653 subjects) found that buprenorphine and buprenorphine-naloxone combination maintenance treatments were associated with less risk of adverse events and improved maternal and fetal outcomes in pregnancy compared with not receiving treatment (Thomas, 2014).

Most studies of buprenorphine have examined the effectiveness of sublingual tablets or film that users must take on a daily basis. An important limitation of these forms of buprenorphine are that users may forget to take the medication every day, may misuse it, or sell it to others. Implantable extended-release

injectable formulations of buprenorphine have been developed to provide longer-acting forms of buprenorphine treatment that are administered in a provider's office.

An RCT (sample size: 163) that compared persons who received four buprenorphine implants over a 6-month period (80 mg per implant) to people who received placebo implants found that people who received the buprenorphine implants were more likely to abstain from opioids and had fewer cravings for opioids (Ling, 2010). A subsequent RCT (sample size: 177) that compared buprenorphine implants to sublingual buprenorphine tablets found that people who received the implants were more likely to abstain from opioids for six months (85.7% vs. 71.9%) (Rosenthal et al., 2016).

An RCT that compared two different dosing regimens for extended-release injectable buprenorphine to a placebo has been completed (sample size: 504). The results have not been published in a peer review journal but were presented at an FDA Advisory Committee meeting (Indivior, 2017). The RCT found that people who received the buprenorphine injection were more likely to abstain from using opioids at least 80% of the 6-week study period than people who received a placebo injection (29% of people receiving 300/300 mg buprenorphine vs. 28% receiving 300/100 mg buprenorphine vs. 2% receiving placebo injections).

Methadone or buprenorphine

A systematic review of 38 observational studies (sample sizes: 18-726 subjects) found that receipt of either methadone or buprenorphine was associated with less injection drug use, less sharing of injection equipment, less exchange of sex for drugs, and lower likelihood of having multiple sex partners among people with OUD (Gowing et al., 2011). Two cohort studies found that receipt of methadone or buprenorphine was associated with lower risk of hepatitis C among persons with OUD (Nolan et al., 2014; Tsui et al., 2014).

Naltrexone

Findings from RCTs that compare naltrexone to a placebo or no treatment differ for the oral formulation and the extended-release intramuscular injection formulation perhaps because the effectiveness of the extended-release formulation does not depend on the patient taking the medication on a daily basis.

A Cochrane review of 13 RCTs (1,158 total subjects; sample sizes: 20-280 subjects) (Minozzi et al., 2011) found that that there was no statistically significant difference between treatment with oral naltrexone and treatment with placebo or no pharmacological agent with respect to retention, abstinence, and side effects.

Findings from three RCTs (sample sizes: 60-308) of extended-release intramuscular injections have found that this newer formulation of naltrexone is more effective than a placebo. Comer et al. (2006) and Krupitsky et al. (2011) found that extended-release naltrexone was associated with longer retention in treatment. Lee et al. (2016) reported that people who received extended-release naltrexone were less likely to use illicit opioids during treatment but found no statistically significant difference one year after treatment ended. Krupitsky et al. (2011) reported that extended-release naltrexone was associated with more opioid-free days. Krupitsky et al. (2011) and Lee et al. (2016) found receipt of extended-release naltrexone was associated with lower likelihood of relapse and Lee et al. (2016) found that people who received extended-release naltrexone had a longer median time to relapse.

Summary of findings regarding the effects of medication versus placebo or no medication: There is clear and convincing evidence from eight systematic reviews and eight RCTs that methadone, buprenorphine (including buprenorphine-nalaxone), and extended-release, intramuscular naltrexone are more effective than a placebo or no treatment with regard to retention in treatment for OUD, reduction in use of illicit drugs, relapse, lower likelihood of engaging in behaviors associated with elevated risk for HIV and hepatitis C, better birth outcomes, and lower mortality rates. Findings from RCTs of oral naltrexone indicate that it does not improve retention in treatment and abstinence from opioids relative to a placebo or no treatment.

Figure 2. Medication Versus Placebo or No Medication

Medication Plus Behavioral Therapy Versus Medication Alone

Several types of behavioral therapy interventions are used to help people control urges to use opioids and remain abstinent and to assist patients in coping with the emotional strife that often accompanies addiction (Dutra et al., 2008). Behavioral therapy interventions can be delivered in different treatment modalities (e.g., inpatient, outpatient) and in a variety of formats (social skills training, individual, group and couples counseling, cognitive-behavioral therapy, contingency management, 12-step facilitation therapy, motivational interviewing, family therapy, and others [Carroll and Onken, 2005]).

Methadone or buprenorphine

In a Cochrane review of 35 RCTs (4,319 participants), Amato et al. (2011b) evaluated the efficacy of providing specific behavioral therapy treatments in conjunction with maintenance MAT medications for OUD, including cognitive behavioral therapy, community reinforcement, contingency management, intensive supportive-expressive therapy, 12-step therapy, interpersonal psychotherapy, and standard counseling. The authors concluded that adding behavioral therapy to maintenance MAT medications does not increase retention in treatment (27 studies, 3124 subjects, sample sizes: 24-542) abstinence from opiates during and after treatment (8 studies, 1002 subjects, sample size 50-335), and compliance (3 studies, 346 subjects, sample sizes: 40-198). The authors also found that adding behavioral therapy to medication maintenance treatment does not reduce psychiatric symptoms or depression (3 studies, 279 subjects, sample sizes: 44-151). However, the authors noted that the control condition in the RCTs typically included a counseling component and that their results should be interpreted as indicating that adding specific, structured, behavioral therapy interventions to standard counseling and maintenance MAT medications does not improve retention, abstinence, compliance, psychiatric symptoms, or depression.

Dugosh (2016) discusses the findings of 3 systematic reviews (Amato, 2011a; Amato, 2011b; Drummond and Perryman, 2007) and 27 recent empirical studies on treatment attendance, retention, and completion; opioid use; and counseling session attendance. The most widely studied behavioral therapy interventions examined in conjunction with maintenance MAT medications for OUD were contingency management and cognitive behavioral therapy, with the majority of studies focusing on the impact of adding behavioral therapy to methadone treatment. The authors conclude that the results generally support the value of

providing behavioral therapy interventions in combination with maintenance MAT medications to treat OUD, although the incremental benefit varied across studies, outcomes, medications, and interventions.

Methadone

In a systematic review of 55 articles, Timko et al. (2016) identified one RCT (sample size 246 subjects) that compared methadone-only patients to patients receiving methadone with contingency management (e.g., rewarding desirable behaviors, punishing undesirable behaviors). The RCT found that persons who received contingency management in addition to methadone were more likely to be retained in treatment at 3 months (81.7% vs. 67.5%).

Naltrexone

CHBRP did not identify any studies that compared receipt of naltrexone alone to receipt of naltrexone plus behavioral therapy.

Summary of findings regarding the effects of medication plus behavioral therapy versus medication alone: There is inconclusive evidence from three systematic reviews of RCTs and controlled observational studies about the impact of combining medication with structured behavioral therapy relative to medication alone or medication with minimal counseling on treatment attendance, retention in treatment, abstinence from opioid use, and psychiatric symptoms. There is insufficient evidence to assess effects on other outcomes, such as mortality, HIV risk behaviors, hepatitis C transmission, or birth outcomes because the systematic reviews did not report findings for these outcomes. Most studies have examined the combination of methadone and behavioral therapy; less is known about the combination of buprenorphine or buprenorphine-naloxone with behavioral therapy. CHBRP did not identify any studies of the combination of naltrexone and behavioral therapy.

Figure 3. Medication Plus Behavioral Therapy Versus Medication Alone

Comparison of Methadone and Buprenorphine or Buprenorphine-Naloxone Combination

A large number of studies have compared the effectiveness of methadone to buprenorphine or buprenorphine-naloxone combination for maintenance MAT treatment of OUD. A smaller number of studies have compared naltrexone to buprenorphine or buprenorphine-naloxone combination treatment. Comparative studies of maintenance MAT medications have examined effects on retention in treatment, abstinence from use of opioids, and birth outcomes. CHBRP did not identify any studies that examined the relative effectiveness of maintenance MAT medications used to treat OUD on transmission of hepatitis C or HIV or on engagement in behaviors that increase risk for contracting hepatitis C or HIV. CHBRP also did not identify any studies of the relative impact of maintenance MAT medications used to treat OUD on mortality.

A Cochrane review by Mattick et al. (2014) compared methadone to different formulations of buprenorphine (i.e., sublingual solution, sublingual tablets, combined buprenorphine-naloxone sublingual

tablet and an implant). The authors found that compared to methadone, buprenorphine retains fewer people in treatment when doses are flexibly delivered (adjusted to participant need) (5 studies; 788 subjects; RR=0.83; 95% CI: 0.72 to 0.95) and at low fixed doses (3 studies; 253 subjects; RR=0.67; 95% CI: 0.52 to 0.87). If fixed medium or high doses are used, buprenorphine and methadone are equally effectiveness for retaining people in treatment (7 studies; 780 subjects; RR=0.87; 95% CI: 0.69 to 1.10) and suppressing illicit opioid use (4 studies; 476 subjects; SMD 0.25; 95%CI: -0.08 to 0.58). However, the authors state that the flexible dose results are more relevant to patient care because fixed doses are rarely used in clinical practice.

A systematic review of four studies (three RCTs and one systematic review; sample sizes: 196-1497 subjects) concluded that the efficacy of buprenorphine is dose dependent. For comparisons at medium-dose ranges, evidence is mixed. Some studies showed similar effects of methadone and buprenorphine but others suggest that methadone improved treatment retention or reduces illicit opioid use. Only one RCT (sample size: 220 subjects) reviewed in this study compared high doses of buprenorphine and methadone, and it showed similar outcomes in terms of days in treatment (mean of 96 and 105 days, respectively) or percentage of patients with 12 or more consecutive negative opioid screens (26% versus 28%, respectively) (Thomas el al., 2014).

Timko et al. (2016) identified three RCTs that compared methadone to buprenorphine or buprenorphine-naloxone. The authors found that methadone was associated with better retention in treatment than buprenorphine-naloxone at 4 months (73.9% versus 45.9%) and at 6 months (74.0% versus 46.0%; 57.6%).

An RCT published after the RCTs included in the systematic reviews compared outcomes for persons treated with buprenorphine or buprenorphine-naloxone to persons treated with methadone for an average of 4.5 years following 24 weeks of treatment (Hser et al., 2016). The authors reported that persons treated with buprenorphine or buprenorphine-naloxone were less likely to abstain from using opioids than people treated with methadone because they received less ongoing treatment after the 24-week trial ended. The RCT found no statistically significant difference in mortality between people treated with the two medications.

In a systematic review of six RCTs (607 participants) that addressed the impact of MAT on people who are addicted to legal opioid prescription drugs (as opposed to heroin and other illegal opioids), Nielsen et al. (2016) found no difference between the effects of methadone and buprenorphine or buprenorphine-naloxone in self-reported opioid use (RR=0.37; 95% CI: 0.08 to 1.63) or opioid positive urine drug tests (RR=0.81; 95% CI: 0.56 to 1.18), retention in treatment (RR=0.69; 95% CI: 0.39 to 1.22), and adverse events (RR=1.10; 95% CI: 0.64 to 1.91).

Three systematic reviews compared the safety of buprenorphine and methadone for maintenance treatment of pregnant women with OUD. Minozzi (2013) and Thomas et al. (2014) found that when the medication was dosed adequately, methadone and buprenorphine or buprenorphine-naloxone combination treatment showed similar reduction in illicit opioid use among pregnant women but that pregnant women treated with methadone were more likely to remain in treatment. Thomas (2014) also found that rates of neonatal abstinence syndrome were similar for infants born to mothers treated with buprenorphine or methadone but that symptoms were less severe for infants whose mothers were treated with buprenorphine. Zedler (2016) found that buprenorphine and buprenorphine-naloxone were associated with lower risk of preterm birth, greater birth weight, and larger head circumference than methadone and that rates of fetal spontaneous deaths and fetal/congenital abnormalities were similar for the two medications. In a review of 4 RCTs, Minozzi et al. (2013) found three RCTs that compared birth weight. Birth weight was higher in the buprenorphine group in the two trials that could be pooled (mean difference (MD) -365.45 g; 95% CI: -673.84 to -57.07; 2 studies, 150 participants). The third double blind

RCT reported that there was no statistically significant difference between buprenorphine and methadone groups (sample size: 18). The reported APGAR score (2 studies, 163 subjects) and number of newborns treated for neonatal abstinence syndrome (3 studies, 166 subjects) did not differ significantly between groups. One RCT (sample size: 131 subjects) comparing methadone with buprenorphine reported side effects. For the mother there was no statistically significant difference; for the newborns in the buprenorphine group there were significantly fewer serious side effects (RR=4.77; 95% CI: 0.59 to 38.49).

Comparison of Naltrexone and Buprenorphine-Naloxone Combination

Two RCTs have compared the effectiveness of extended-release naltrexone and buprenorphine-naloxone. One RCT assessed outcomes after 12 weeks of treatment (Tanum et al., 2017).[24] The authors found no statistically significant difference in the length of time people remained in treatment or their abstinence from use of illicit opioids (as measured by negative urine tests). Persons who received extended-release naltrexone reported less craving for heroin but were more likely to report symptoms of withdrawal. A second RCT examined outcomes after 24 weeks of treatment (Lee et al., 2018). The authors found that participants were less likely to successfully initiate treatment with extended-release naltrexone that with buprenorphine-naloxone which led extended-release naltrexone patients to have a higher relapse rate than patients who received buprenorphine-naloxone. This finding is not surprising because extended-release naltrexone cannot be initiated until a person has fully detoxified from opioids, whereas buprenorphine-naloxone treatment can begin before detoxification is complete. Among patients who successfully initiated treatment, there were no statistically significant differences in relapse rates or in abstinence from use of opioids as (measured by negative urine tests and self-report).

Summary of findings regarding the relative effectiveness of different medications used to treat OUD: There is inconclusive evidence from six systematic reviews and one RCT published after the systematic reviews about the impact of methadone relative to buprenorphine or buprenorphine-naloxone on retention in maintenance treatment. Systematic reviews have reached different conclusions about the relative effectiveness of methadone and buprenorphine for retention in treatment and abstinence from opioids. The relative effectiveness of the two medications may be dose dependent because some studies find that methadone and buprenorphine are equivalent when patients are given high doses of buprenorphine but not when they are given low doses. There is limited evidence that buprenorphine and buprenorphine-naloxone are associated with better birth outcomes than methadone but women receiving buprenorphine or buprenorphine-naloxone were less likely to remain in treatment than women who receive methadone. Two RCTs that compare extended-release naltrexone to buprenorphine-naloxone have found that people have more difficulty initiating treatment with extended-release naltrexone but that outcomes of treatment with the two medications are similar for persons who successfully initiate treatment.

Figure 4. Relative Effectiveness of Different Medications Used to Treat Opioid Use Disorder

[24] CHBRP identified one observational study that compared birth outcomes for pregnant women treated with implantable naltrexone to birth outcomes for pregnant women treated with methadone and buprenorphine (Kelty and Hulse, 2017). CHBRP did not include this study in its review because the FDA has not approved implantable naltrexone for use in the United States.

Harms Associated with Use of Maintenance MAT Medications

Patients who take methadone or buprenorphine to treat OUD may experience side effects that are similar to those of opioids, such as nausea, vomiting, constipation, muscle aches, cramps, constipation, fever, cravings, irritability, and inability to sleep (SAMHSA, 2018). People using methadone may also experience difficulty breathing, lightheadedness, hives, rash, chest pain, rapid heart rate, and hallucinations (SAMHSA, 2018). People taking extended-release injectable formulations of buprenorphine or naltrexone or implantable buprenorphine may also experience reactions at the injection site, such as bruising, itching, pain, or swelling (Indivior, 2017; Rosenthal et al., 2016).

There is also a risk that people will misuse methadone or buprenorphine due to their opioid effects (SAMHSA, 2018). This risk is higher with buprenorphine than methadone because people are often prescribed a supply of buprenorphine to take on their own, whereas people receiving methadone are usually required to take their medication at a methadone clinic. There is also less risk of misuse of extended-release injectable formulations of buprenorphine and naltrexone because they are administered in physicians' offices.

Initiation and discontinuation of treatment with naltrexone carries added risk of harm. Unlike methadone and buprenorphine, which can be used safely while a patient continues to use opioids, patients must withdraw from all opioids before beginning treatment with any formulation of naltrexone. Some patients are unable to do this and may overdose on opioids during the withdrawal period. Lee et al. (2018) found a higher risk of overdose during initiation of treatment among persons slated to receive extended-release injectable naltrexone than among people receiving orally administered buprenorphine. In addition, patients treated with naltrexone who discontinue treatment and resume use of opioids may be sensitive to lower doses of opioids, which could increase their risk of overdose (SAMHSA, 2015). Because relapse is common among people who receive all forms of treatment for OUD, risk of overdose when a person resumes consumption of opioids should be considered when treatment decisions are made (Saucier et al. 2018).

Harms associated with use of maintenance MAT medications to treat OUD must be weighed against the harms associated with continued use of opioids. As discussed previously, people who use medication to treat OUD have lower risks of mortality, HIV transmission, hepatitis C infection, and poor birth outcomes relative to people who are not treated with a maintenance MAT medication.

Effects of Utilization Management on Use of Maintenance MAT Medication and Outcomes

CHBRP found only one study that addressed the impact of utilization management on use of medications to treat OUD or patient outcomes. Clark et al. (2014) examined the effects of a change in the Massachusetts Medicaid program's prior authorization requirements for coverage of buprenorphine-naloxone. Under the policy, prior authorization was required for doses greater than 16 mg per day. After the prior authorization policy was implemented the number of people prescribed doses of buprenorphine-naloxone greater than 24 mg per day decreased while the number prescribed lower doses per day increased. The relapse rate increased temporarily and the increase was most pronounced among people who received doses greater than 16 mg/day. The relapse rate returned to previous levels within 3 months. The authors did not report any other outcomes. A major limitation of this study is that it assessed the effects of instituting a prior authorization requirement. It does not address the impact of prohibiting prior authorization. This study also does not provide any information about the effects of other utilization management techniques.

Summary of findings regarding the effects of utilization management: There is *insufficient* evidence to assess the impact of utilization management on use of medication to treat opioid use disorder and patient outcomes.

Summary of Findings

Table 3 summarizes evidence of the effectiveness of medication for maintenance treatment of OUD. Evidence is reported separately for (1) medication versus a placebo or no treatment, (2) medication plus behavioral therapy versus medication alone, and (3) comparison of different medications used to treat OUD. Findings differ substantially by comparison. There is clear and convincing evidence from multiple RCTs that medications 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 from observational studies that receipt of medication reduces mortality and morbidity. Depending on the outcome, there is either inconclusive or insufficient evidence to determine whether adding a structured behavioral therapy intervention to medication improves the outcome. With the exception of birth outcomes, where limited evidence indicates that buprenorphine and buprenorphine-naloxone are more effective than methadone, evidence about the relative effectiveness of these medications is inconclusive or insufficient. RCTs that have compared extended-release naltrexone to buprenorphine-naloxone have found that persons have more difficulty initiating treatment with extended-release naltrexone but that outcomes for the two medications are similar among people who successfully initiate treatment.

Table 3. Summary of Findings

Outcome	Medication vs. Placebo or No Treatment	Medical + Behavioral Therapy vs. Medication Alone	Comparison of Different Medications
Retention in treatment	Clear and convincing evidence favors medication	Inconclusive evidence	Inconclusive evidence
Use of opioids	Clear and convincing evidence favors medication	Inconclusive evidence	Inconclusive evidence
HIV risk behaviors	Preponderance of evidence favors medication	Insufficient evidence	Insufficient evidence
Hepatitis C	Preponderance of evidence favors medication	Insufficient evidence	Insufficient evidence
Birth outcomes	Clear and convincing evidence favors medication	Insufficient evidence	Limited evidence favors buprenorphine
Mortality	Preponderance of evidence favors medication	Insufficient evidence	Insufficient evidence

Source: California Health Benefits Review Program, 2018.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2384 would require DMHC-regulated health plans, including non-County Organized Health Systems (COHS) Medi-Cal Managed Care plans, and CDI-regulated policies that include an outpatient prescription drug (OPD) benefit to cover: (1) medications approved by the FDA for treatment of opioid use disorder (OUD) including maintenance drugs like buprenorphine, combination buprenorphine-naloxone, and extended-release naltrexone, plus emergency opioid reversal drug naloxone; (2) methadone clinic outpatient services; and (3) outpatient behavioral therapy, when delivered as part of medication-assisted treatment (MAT). AB 2384 would also prohibit medical necessity review, prior authorization requirements, step therapy, fail first, or other utilization management tools that may conflict with a course of prescribed treatment, coverage denials based on prior success or failure with MAT, limitation of coverage to predesignated facilities, limits related to visits, days of coverage, scope or duration of treatment, or other similar limits, or annual or lifetime dollar limits of financial requirements different from those relevant to other covered illnesses.

Approximately 95.6% of enrollees in DMHC-regulated plans and CDI-regulated policies have OPD coverage and would be subject to AB 2384 (Table 1). Of the remaining enrollees, 1.4% have no OPD benefit and 3.0% have OPD coverage that is not regulated by DMHC or CDI. AB 2384 does not address these forms of health insurance and so no mandate-related change in benefit coverage or utilization would be expected for these enrollees. See Appendix D for a further discussion of OPD coverage.

This section reports the potential incremental impacts of AB 2384 on estimated baseline benefit coverage, utilization, and overall cost. The benefit coverage, utilization and cost impacts discussed here are based upon published evidence (see Appendix C) and several key assumptions in addition to those described in the *Policy Context* section about the scope of AB 2384.

The estimates are based upon the following core assumptions:

- Prior to AB 2384, approximately 20% of enrollees with OUD receive MAT. AB 2384 is estimated to increase this proportion to 25% of enrollees with OUD receiving MAT. The increase is attributed to the removal of utilization management barriers like prior authorizations, limits, and fail-first requirements resulting in an overall increase in use of OUD treatment services including behavioral therapy and medication when associated with MAT. CHBRP anticipates that the removal of utilization management requirements would increase use to a level that is commensurate with the typical pattern of care seen in patients already getting OUD treatment through their commercial insurance plans in terms of dosing, frequency of refills, and patient needs. CHBRP does not assume that patients are receiving less than the standard of care once they are able to secure OUD treatment, even if they previously faced utilization management protocols that limited their ability to seek care.
- In the postmandate absence of utilization management tools, CHBRP assumes utilization of MAT by persons with OUD will increase from 20% to 25% among enrollees with health insurance subject to AB 2384. However, CHBRP assumes that remaining structural barriers as well as attitudinal barriers (see Background section) will continue to dampen utilization of MAT among the other 75% of enrollees with OUD going without treatment.
- No change in MAT utilization for existing MAT users is expected as a result of AB 2384 and new MAT users are expected to have a MAT utilization pattern similar to existing MAT users.
- Due to the removal of utilization management barriers for behavioral therapy and naloxone associated with MAT, and the requirement in AB 2384 to allow for out-of-network services, CHBRP assumed, after consultation with a content expert, that the use of behavioral therapy and

naloxone prescribed to MAT patients for overdose reversal would increase for new and existing MAT users by 5% when compared to current use of behavioral therapy services and naloxone prescriptions. This increase does not apply to other MAT services. Postmandate, CHBRP assumed that new naloxone prescriptions would be split evenly between the less expensive nasal spray and the more expensive auto-injector option due to the removal of utilization management tools.

- The actual average cost for prescriptions and visits for buprenorphine and methadone in both commercial market and Medi-Cal managed care plans is expected to be the same. This assumption is due to constraints on legal providers of methadone and buprenorphine, as well as the Drug Medi-Cal carve out. CHBRP assumes that the vendors available for the treatments described are paid rates more typical of a commercial plan and so prices paid by Medi-Cal managed care plans are assumed to be equivalent to the prices paid by commercial plans in MarketScan data for those services. All other MAT service costs, including naloxone, behavioral therapy, and medical services related to OUD will be subject to existing differences between Medi-Cal and commercial unit costs.
- The population subject to the mandated offering includes enrollees in DMHC-regulated plans and CDI-regulated policies for large-group, small-group, individual marketplace plans; CalPERS plans; and Medi-Cal. Estimated Medi-Cal MAT and OUD prevalence is expected to be higher than the commercially insured population. A recent report (MACPAC, 2017) states that the prevalence rate is approximately two times that of the commercial population. CHBRP estimates a 0.654% OUD prevalence rate for commercial populations and 1.36% OUD prevalence rate for Medi-Cal with a population-wide OUD prevalence of 0.891%.
- Baseline MAT drug and counseling costs and associated utilization were based on 2016 MarketScan® commercial claims and enrollment data for the state of California with few exceptions.
- Methadone is one of the accepted MAT drugs but is not in MarketScan when used for OUD. CHBRP used national figures of methadone users reported by Alderks (2017) to estimate the prevalence rate of methadone users. CHRBP estimates the baseline average methadone cost is $18 per day.
- Methadone usage rate was based on an overall prevalence of methadone as reported by SAMHSA (Alderks, 2017). The report shows methadone represents 80% of MAT usage in federally certified methadone outpatient treatment programs (methadone clinics), but excludes MAT outside of methadone clinics. Inclusive of treatment outside of methadone clinics, methadone was assumed to represent 60% of MAT usage.

CHBRP applied estimated utilization and cost offsets based on published evidence (Mohlman et al., 2016) on the impact of MAT maintenance treatment on emergency room use, inpatient services, outpatient physician services, and other OUD-related services.

For further details on the underlying data sources and methods, please see Appendix C.

Baseline and Postmandate Benefit Coverage

Current coverage of MAT-related drugs and behavioral therapy services for OUD was determined by a survey of the largest (by enrollment) providers of health insurance in California, including DMHC-regulated Medi-Cal managed care plans. Responses to this survey represent 73% of enrollees with commercial market health insurance and 49.4% of enrollees in the DMHC-regulated Medi-Cal managed

care market that can be subject to state mandates. Due to the Drug Medi-Cal carve out, prior to AB 2384 there was no coverage in the regulated Medi-Cal Managed Care plans for the services required by AB 2384. As noted in Table 1, 7% of enrollees with commercial health insurance have fully compliant coverage for MAT for OUD due to not having an OPD benefit (and so not requiring change to be compliant with AB 2384). To be fully compliant, health insurance that includes an OPD benefit need to cover all of the FDA-approved drugs and behavioral therapy services described in AB 2384 without any utilization management requirements. Of commercial enrollees, 93% have health insurance that is partially compliant with AB 2384 because they have an OPD benefit, cover some or all of the MAT drugs and behavioral therapy, and have utilization management restrictions attached to their coverage. Table 4 demonstrates that almost all enrollees have on-formulary coverage for the drugs and medical benefit coverage for outpatient services and behavioral therapy services mentioned in AB 2384. Table 5 and Table 6 demonstrate that most enrollees are not subject to medical necessity review or prior authorization for MAT-related drugs or behavioral therapy. However, utilization management in existence for approximately 70% of enrollees via in-network restrictions and limits on utilization could impact access to MAT to treat OUD.

Currently, 0% of Medi-Cal beneficiaries enrolled in managed care plans have health insurance fully compliant with the proposed mandate due to the existing Drug Medi-Cal carve out. Of Medi-Cal managed care enrollees, 100% were reported to be in plans with benefit coverage for the FDA-approved drugs and behavioral therapy, but all were subject to utilization management requirements that would be prohibited by AB 2384. CHBRP assumes that utilization management includes referral to the appropriate Drug Medi-Cal carve-out plan in each county, whether delivered via fee-for-service, specialty plan, or ODS waiver program.

CHBRP anticipates that the Drug Medi-Cal carve out, when combined with the new requirement for Medi-Cal managed care plans to cover the drugs on the list without utilization management, would create duplicate coverage for a previously carved out service. Because AB 2384–compliant Medi-Cal managed care plans would need to remove utilization management requirements and cover all approved MAT drugs and services, there could be an incentive for current Medi-Cal enrollees with OUD who use services through a carve-out Drug Medi-Cal program would experience better access to drugs and services in the managed care plans when compared to the carve-out program that could continue using formulary restrictions and utilization management to limit use of certain services, drugs, brands, etc.

Table 4. AB 2384 Treatment-Specific Baseline Benefit Coverage

Enrollees with Commercial Health Insurance (a) Subject to AB 2384 with…	
On-formulary coverage for methadone	99.94%
On-formulary coverage for buprenorphine	98.46%
On-formulary coverage for combination buprenorphine-naloxone	98.46%
On-formulary coverage for extended-release naltrexone	98.46%
On-formulary coverage for naloxone (b)	99.94%
Coverage for outpatient behavioral therapy for substance use disorder	96.93%

Source: California Health Benefits Review Program, 2018.
Notes: (a) MAT related coverage for Medi-Cal beneficiaries is generally carved out from their DMHC-regulated plan coverage but available through Drug Medi-Cal; (b) For emergency use.

Table 5. AB 2384 Medication-Specific Baseline Benefit Coverage Utilization Management

Enrollees with Commercial Health Insurance (a) Subject to AB 2384 with Baseline On-formulary Coverage for the Mediation that is…	Methadone	Buprenorphine	Combination Buprenorphine-Naloxone	Extended-release Naltrexone	Naloxone (b)
Subject to medical necessity review	7.13%	5.62%	6.65%	0.00%	5.62%
Limited to prescriptions written by in-network providers	68.81%	69.84%	74.43%	68.81%	68.81%
Subject to prior authorization requirements	6.78%	5.62%	1.03%	0.00%	0.00%
Subject to step therapy, fail first, or other protocols that may conflict with a prescribed course of treatment	10.19%	4.88%	0.00%	0.00%	4.88%
Subject to coverage denials based on prior success or failure with the medication-assisted treatment	6.33%	1.03%	0.00%	0.00%	0.00%
Limited to fulfillment at in-network pharmacies and/or to other pre-designated facilities	79.77%	76.84%	76.67%	70.02%	78.15%
Subject to limits (number of visits, days of coverage, scope or duration of treatment, etc.).	22.39%	27.14%	28.00%	19.73%	29.47%
Subject to annual or lifetime dollar limits. If any, please indicate the applicable limits	0.00%	0.00%	0.00%	0.00%	0.00%
Subject to financial requirements different from those relevant to other covered illnesses. If any, please indicate the differing requirements.	0.00%	0.00%	0.00%	0.00%	0.00%

Source: California Health Benefits Review Program, 2018.
Notes: (a) MAT related coverage for Medi-Cal beneficiaries is generally carved out from their DMHC-regulated plan coverage but available through Drug Medi-Cal; (b) For emergency use.

Table 6. AB 2384 Behavioral Therapy for Substance Use Disorder Baseline Benefit Coverage Utilization Management

Enrollees with Commercial Health Insurance (a) Subject to AB 2384 with Baseline for Behavioral Therapy for Substance Use Disorder that is…	
Subject to medical necessity review	3.09%
Limited to in-network providers	74.43%
Subject to prior authorization requirements? If any, please include the protocol with your response.	1.48%
Subject to step therapy, fail first, or other protocols that may conflict with a prescribed course of treatment. If any, please include the protocol with your response.	1.48%
Subject to coverage denials based on prior success or failure with the medication-assisted treatment	0.00%
Limited to fulfillment at pre-designated facilities	67.19%
Subject to limits (number of visits, days of coverage, scope or duration of treatment, etc.). If any, please indicate the applicable limits.	1.48%
Subject to annual or lifetime dollar limits. If any, please indicate the applicable limits	0.00%
Subject to financial requirements different from those relevant to other covered illnesses. If any, please indicate the differing requirements.	0.00%

Source: California Health Benefits Review Program, 2018.
Notes: (a) MAT related coverage for Medi-Cal beneficiaries is generally carved out from their DMHC-regulated plan coverage but available through Drug Medi-Cal.

Baseline and Postmandate Utilization

Based on current MarketScan analysis, enrollees with OUD with coverage for MAT in commercial plans use approximately 10.14 methadone, 4.91 buprenorphine, 5.97 combination buprenorphine-naloxone, 2.83 naltrexone, and 1.10 naloxone prescriptions/services per year (see Table 1). Enrollees with OUD could be receiving treatment through multiple modalities within a 1-year period of time, but are typically receiving one to two distinct treatments at any given time. For example, someone who is receiving buprenorphine treatment alongside behavioral therapy may also have obtained naloxone preventively for overdose reversal in emergency situations.

Postmandate utilization of MAT maintenance drugs would be expected to increase by 25% due to the removal of utilization management requirements in 93% of plans resulting in new users of services. However, the rates of use for new users would mirror that of the premandate user population because CHBRP anticipates that the existing enrollees receiving MAT services have been able to establish a stable treatment pattern based upon existing utilization management. However, Naloxone use is anticipated to increase per user by 5% for existing MAT users due to the reduction in utilization management tools, resulting in a total 25% increase overall in use (to 1.15 prescriptions per user per year). In addition, Behavioral therapy is anticipated to increase by 31% in overall visit per year based upon existing MAT users experienced fewer barriers to behavioral therapy due to removal of utilization management and in-network restrictions, plus new users who will use behavioral therapy services related to their new receipt of MAT (see Table 1).

Baseline and Postmandate Per-Unit Cost

Table 7 provides an estimate of 30-day costs of each type of FDA-approved MAT drug based upon MarketScan analysis of current use by commercial enrollees with OUD. The actual unit cost of services would not be anticipated to change postmandate, though the frequency of services would increase due to new users and removal of utilization management. Due to the removal of utilization management related to brand-name drug use, CHBRP assumes that emergency doses of naloxone provided to MAT patients for "rescue" overdose reversal purposes would shift to easier to use methods due to lack of utilization management. The postmandate increase in naloxone prescribed to MAT patients would be split so that 50% of prescriptions would be for nasal spray or pre-filled syringes and 50% would be for the more expensive auto-injector versions of naloxone.

Table 7. AB 2384 Medication Specific Unit Costs

Medication	30-Day Supply Cost	Average # of 30-Day Supply Prescriptions Filled per Year	Annualized Unit Cost per Enrollee
Methadone	$553	10.14	$5,610
Buprenorphine	$283	4.91	$128
Combination Buprenorphine Naloxone	$375	5.97	$312
Extended-release Naltrexone	$219	2.83	$51
Naloxone* (Auto-Injector)	$4,603	1.00	$4,603
Naloxone* (Spray, Generic, Injection)	$94	1.00	$94

Source: California Health Benefits Review Program, 2018.
Notes: *For emergency use.

Baseline and Postmandate Expenditures

Table 8 and Table 9 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).

AB 2384 would increase total net annual expenditures by $24,668,000 or 0.0159% for enrollees with DMHC-regulated plans and CDI-regulated policies. This increase is primarily driven by an increase of $16,932,000 in spending by Medi-Cal managed care plans due to the new requirements that appear to duplicate currently carved out services for MAT. This new spending is for existing enrollees with OUD who may not have had access to MAT due to utilization management tools applied to benefit coverage available through the Drug Medi-Cal carve out. The commercial plans covered by AB 2384 are estimated to experience a lower increase in expenditures due to the increased access to MAT and the cost offsets described earlier. CHBRP anticipates that the duplication of coverage between Drug Medi-Cal and DMHC-regulated plans would result in an increase in utilization of MAT through Medi-Cal managed care plans, partially due to the removal of utilization management restrictions and limits that would still be allowed and applied in the Drug Medi-Cal program are not subject to the proposed mandate. CHBRP assumes that Medi-Cal managed care enrollees who were not using MAT services in Drug Medi-Cal will take advantage of increased availability due to AB 2384 requiring coverage of MAT without utilization management. Utilization management would still be in effect on the Drug Medi-Cal carve out because that program is not subject to AB 2384.

Premiums

Changes in premiums as a result of AB 2384 would vary by market segment (Table 9). In the commercial market, premium increases are higher in the individual market and small group when compared to the large group market for both CDI and DMHC-regulated plans. The largest increase is among Medi-Cal managed care plans due to the duplication with Drug Medi-Cal and new services provided by Medi-Cal managed care plans.

Overall, there is a net 0.0152% increase in total health insurance premiums paid by employers, enrollees, and Medi-Cal for newly covered benefits. Payers for enrollees in commercial plans are estimated to experience an increase in premiums of between 0.0026% and 0.0054%, depending on the market segment (Table 9). However, Medi-Cal managed care plans would experience a 0.0679% increase due to the duplicate coverage and removal of utilization management that would incentivize new services to be provided by Medi-Cal managed care plans instead of Drug Medi-Cal.

Enrollee Expenses

AB 2384-related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9) with health insurance that would be subject to AB 2384 expected to use the relevant treatments or prescription drugs during the year after enactment.

CHBRP projects no change to copayments or coinsurance rates for users but does project an increase in utilization of treatment and prescription drugs and therefore an increase in total enrollee cost sharing. Enrollee out-of-pocket expenses are expected to increase by 0.0223% overall. Cost sharing for the services mandated under AB 2384 cannot be different than medical services or other mental health services already covered by the plan. Due to limitations on Medi-Cal managed care plans use of cost

sharing, the enrollee cost sharing changes are concentrated on the commercial market and relate to the overall increase in service use and associated cost sharing for new services used by existing MAT users (naloxone and behavioral therapy) and new MAT user services.

Increases in enrollee per member per month expenses for covered benefits are estimated to increase from a low of $0 in Medi-Cal managed care plans to a high of $0.0198 in both DMHC and CDI-regulated small-group commercial plans (Table 9).

Out-of-Pocket Spending for Covered and Noncovered Expenses

When possible, CHBRP estimates the marginal impact of the bill on out-of-pocket spending for covered and noncovered expenses, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and coinsurance). CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

It is possible that some enrollees incurred expenses related to treatment and prescription drugs for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

Generally, the literature suggests that OUD treatment with methadone, buprenorphine, naloxone, or naltrexone lead to better outcomes and reduced overall spending when compared with no use of MAT by OUD (McCarty, 2010; Tkacz, 2014). Despite sizeable costs of MAT services, the MAT recipients in the articles mentioned above experienced 43% lower spending on average for inpatient and outpatient services. These studies suggest in aggregate that MAT services are likely to result in short- and long-term savings (see the *Long-Term Public Health Impacts* section). CHBRP used literature focused on utilization change due to MAT to inform its cost model estimates.

To estimate the cost offsets for MAT likely to occur due to AB 2384, CHBRP relied on one article that isolates the impact of MAT on health services utilization in the Vermont Medicaid program (Mohlman, 2016). The article suggests that increases in MAT are offset by decreases in spending on inpatient days and stays, emergency room visits, and imaging. However, Mohlman found an increase in the use of other services, including surgical appointments and primary and specialty care services.

These cost offsets for new users only are reflected in Table 1 and the estimates for expenditures and premium changes in 2019. It should be noted that the commercial cost offsets are much larger due to the higher prices paid for services by commercial plans, while Medi-Cal managed care plans have been successful in negotiating or setting lower prices for inpatient, emergency room, and ambulatory care services like specialty and primary care visits. However, CHBRP used commercial rates to estimate the costs of methadone and buprenorphine for Medi-Cal managed care enrollees because supply of both is constrained by certification and licensure requirements (see *Background*).

For the combined commercial and CalPERS market segments, 4,872 more enrollees using MAT will cost an additional $31,197,000, but the added cost will be offset by a reduction of $23,461,000 (resulting from less ED visits, hospitalizations, etc). For the Medi-Cal segment of the DMHC-regulated plans market, 5,107 more enrollees using MAT will cost an additional $26,813,000, but the cost will be offset by a reduction of $9,881,000 (resulting from less ED visits, hospitalizations, etc).

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would 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.

Postmandate Changes in the Number of Uninsured Persons[25]

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 8, and Table 9), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 2384.

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 2384.

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

Currently, the carved out Drug Medi-Cal benefit is used to deliver the services covered by AB 2384. Drug Medi-Cal does cover all of the MAT drugs and services, sometimes with utilization management restrictions. Due to the duplication in coverage proposed by AB 2384 and prohibition of utilization management for Medi-Cal Managed Care Plans, CHBRP anticipates new users of MAT (who had previously been discouraged from MATuse by utilization management) will receive care from Medi-Cal Managed Care plans instead of Drug Medi-Cal due to the relative ease of obtaining treatments without utilization management or restrictions. CHBRP estimates that this overlap or duplication in coverage will result in new MAT patients using services through Medi-Cal managed care plans, while existing MAT patients will continue to use services via Drug Medi-Cal.

[25] See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Table 8. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2019

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market)[a]			Publicly Funded Plans			Commercial Plans (by Market)[a]			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65)[c]*	*MCMC (65+)[c]*	*Large Group*	*Small Group*	*Individual*	**Total**
Total enrollees in plans/policies subject to state mandates[d]	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Total enrollees in plans/policies subject to AB 2384	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Average portion of premium paid by Employer	$482.65	$343.93	$0.00	$505.74	$276.66	$808.46	$557.12	$459.26	$0.00	$103,945,637,000
Average portion of premium paid by Employee	$122.24	$158.45	$588.53	$82.33	$0.00	$0.00	$175.81	$167.30	$459.20	$36,625,181,000
Total Premium	**$604.88**	**$502.38**	**$588.53**	**$588.07**	**$276.66**	**$808.46**	**$732.93**	**$626.56**	**$459.20**	**$140,570,818,000**
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	$48.13	$111.60	$159.72	$50.14	$0.00	$0.00	$133.93	$176.39	$112.74	$14,896,952,000
Enrollee expenses for noncovered benefits[e]	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
	$653.02	**$613.98**	**$748.25**	**$638.21**	**$276.66**	**$808.46**	**$866.86**	**$802.95**	**$571.95**	**$155,467,770,000**

Source: California Health Benefits Review Program, 2018.

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

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) 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 currently covered by insurance. This only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

Table 9. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2019

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market)[a]			Publicly Funded Plans			Commercial Plans (by Market)[a]			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs[b]*	*MCMC (Under 65[c])*	*MCMC (65+)[c]*	*Large Group*	*Small Group*	*Individual*	**TOTAL**
Enrollee Counts										
Total enrollees in plans/policies subject to state Mandates[d]	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Total enrollees in plans/policies subject to AB 2384	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Premium Costs										
Average portion of premium paid by Employer	$0.0171	$0.0186	$0.0000	$0.0139	$0.1879	$0.1879	$0.0146	$0.0199	$0.0000	$19,774,000
Average portion of premium paid by Employee	$0.0043	$0.0086	$0.0270	$0.0023	$0.0000	$0.0000	$0.0046	$0.0073	$0.0235	$1,565,000
Total Premium	$0.0215	$0.0272	$0.0270	$0.0162	$0.1879	$0.1879	$0.0192	$0.0272	$0.0235	**$21,339,000**
Enrollee Expenses										
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	$0.0166	$0.0198	$0.0197	$0.0125	$0.0000	$0.0000	$0.0149	$0.0198	$0.0171	$3,329,000
Enrollee expenses for noncovered benefits[e]	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Total Expenditures	$0.0381	$0.0470	$0.0466	$0.0286	$0.1879	$0.1879	$0.0341	$0.0470	$0.0405	**$24,668,000**
Postmandate Percent Change										
Percent change insured premiums	0.0036%	0.0054%	0.0046%	0.0027%	0.0679%	0.0232%	0.0026%	0.0043%	0.0051%	0.0152%
Percent Change total expenditures	0.0058%	0.0077%	0.0062%	0.0045%	0.0679%	0.0232%	0.0039%	0.0059%	0.0071%	0.0159%

Source: California Health Benefits Review Program, 2018.

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

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) 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 currently covered by insurance. This only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

PUBLIC HEALTH IMPACTS

The public health impact analysis estimates the impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate) of AB 2384, which mandates coverage of medication-assisted treatment (MAT) for opioid use disorder (OUD) and prohibits carriers' use of utilization management tools related to MAT. This section focuses on the bill's short-term impact[26] on health outcomes and disparities related to OUD. See *Long-Term Public Health Impacts* for discussion of premature death, economic loss, and social determinants of health.

Estimated Public Health Outcomes

Primary health outcomes relevant to AB 2384 include retention in treatment, use of illicit drugs, opioid overdose and overdose-related mortality, likelihood of engaging in behaviors associated with elevated risk for HIV and hepatitis C, and birth outcomes.

As presented in the *Medical Effectiveness* section, there is strong evidence that methadone, buprenorphine (including buprenorphine-naloxone), and extended-release, intramuscular naltrexone are more effective than a placebo or no treatment with regard to:

- improving retention in treatment,
- reducing use of illicit drugs,
- decreasing the behaviors associated with elevated risk for HIV and hepatitis C,
- improving birth outcomes, and
- reducing opioid-related mortality.

Naloxone alone is effective in reversing opioid overdose. There is insufficient evidence regarding the impact of prohibiting utilization management strategies on MAT uptake and retention.

The *Benefit Coverage, Utilization, and Cost Impacts* section estimated that the commercial insurance market has 132,610 enrollees with OUD (0.654% prevalence rate) and Medi-Cal has 138,835 beneficiaries (enrolled in DMHC-regulated plans) with OUD (1.36% prevalence rate). Of those, CHBRP assumes 20% (about 19,400) obtain MAT at baseline. This number represents only the commercial market because Medi-Cal carves out OUD treatment from Medi-Cal managed care plan contracts. CHBRP projects that, postmandate, the number of enrollees receiving MAT-related medications and associated behavioral therapy would increase by 25% due to the bill's prohibition of utilization management tools: 4,872 new commercial users and 5,107 new Medi-Cal managed care users of MAT medications; and 2,216 new commercial users and 2,323 new Medi-Cal managed care users of associated behavioral therapies. (The groups of new medication and new behavioral therapy users are not mutually exclusive.) CHBRP projects a postmandate increase in Medi-Cal managed care enrollees receiving MAT due to new double coverage (MMC and Drug Medi-Cal) where utilization management barriers are removed from Medi-Cal managed care plans, but still exist in Drug Medi-Cal.

Thus, for those additional 9,979 MAT medication users and 4,539 behavioral therapy users, CHBRP anticipates a decrease in illicit drug use, opioid overdose, overdose-related mortality, poor maternal/fetal outcomes, and related health services. CHBRP also projects some decrease in serious infectious diseases such as HIV and hepatitis C. For example, national estimates of hepatitis C infection rates among injection drug users ranges from 60% to 90% (Tsui et al., 2014) indicating a high likelihood of transmitting the infection when sharing contaminated drug equipment. In 2015, about 18% of California females with HIV contracted the infection through injection drug use compared with 5% of HIV+ males

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

(although males comprise 88% of the HIV population) (CDPH, 2015). As indicated by the evidence-based literature, MAT for OUD reduces risky behaviors leading to HIV and hepatitis C transmission; thus, injection drug users who use MAT could avert contracting HIV and/or hepatitis C or prevent transmission to others.

In addition, aforementioned research showed decreased utilization of emergency room use and hospitalizations for MAT users as compared with people untreated for OUD (Mohlman et al., 2016). In the case of AB 2384, CHBRP estimates that, per year, each MAT user would have one less emergency room visit, one less inpatient day, one additional surgical visit, and five additional primary care visits (see Table 15 in Appendix C for estimated changes in use of specific health services.)

The public health impact of AB 2384 may be less than some anticipate for several reasons. In addition to potential insurance barriers like utilization management (Jones et al., 2015), other significant structural and attitudinal barriers contribute to lower-than-desired MAT rates. As discussed in the *Background on Medication-Assisted Treatment for Substance Use Disorders* section, attitudinal barriers are strong deterrents to seeking treatment. Namely, the nature of addiction precludes people with OUD from recognizing their need for help, with an estimated 11% seeking treatment in the first year after onset of the disorder and 24% within 10 years after onset (Blanco et al., 2013). Stigma from family, friends, employers, and some providers in acknowledging addiction or the validity of MAT produces another significant attitudinal barrier for people with OUD. Moreover, structural barriers in California prevent some who want MAT from obtaining it due to a mismatch between MAT provider supply and patient demand (Clemans-Cope et al., 2018; Knudsen et al., 2016).

In the first year postmandate, CHBRP projects that AB 2384 would decrease undesirable health outcomes associated with OUD (illicit drug use; opioid overdose; overdose-related mortality; poor maternal/fetal outcomes; HIV and hepatitis C transmission) and change associated health services use among the new MAT users (9,979 medication users and 4,539 behavioral therapy users). This estimate is based on and clear and convincing evidence that methadone, buprenorphine (including buprenorphine-naloxone), and extended-release, intramuscular naltrexone are medically effective in treating OUD.

Impact on Disparities[27]

Disparities are differences between groups that are modifiable, and insurance benefit mandates that impose coverage parity among state-regulated plans and policies may change an existing disparity.[27] There are a number of disparities in the prevalence of OUD and negative health outcomes experienced across race/ethnicity, age, and gender; however, the disparities vary within demographic categories according to the health outcome and opioid type. For example, in California, mortality rates are highest among Native Americans and whites for *all* opioids (Table 2). However, the California Opioid Overdose Surveillance Dashboard also shows that blacks have the highest rate of hospitalizations for opioid-related mortality (14.7/100,000) followed by whites (13/100,000), Native Americans (6.5/100,000), Latinos (4.8/100,000), and Asians 1/100,000) (CDPH, 2018).

The Dashboard also shows that younger cohorts (aged 20-29 years) have among the highest crude rates of emergency department visits for *all* opioid-overdose (about 14.5/100,000) of any age group, only exceeded by those aged 50 to 59 years (16-19/100,000). Another age disparity exists according to heroin use and consequences. Those cohorts aged 20 to 39 years have the highest heroin-overdose mortality rate (2.3-3.7/100,000) as compared with the remaining age cohorts (0-2/100,000) (CDPH, 2018). The

[27] For details about CHBRP's methodological approach to analyzing disparities, see http://www.chbrp.org/analysis_methodology/docs/Estimating Impacts on Racial and Ethnic Disparities FINAL.pdf.

National Survey on Drug Use and Health reported that 7.41% of Californians aged 18-25 years needed, but did not receive treatment for illicit drug use at a specialty facility, which was more than twice the rate of all Californians needing treatment (3.11%) (SAMSHA, 2016).

Although males and females have about the same rate of emergency department visits for opioid overdoses (*excluding heroin)* (11/100,000 and 11.5/100,000, respectively), *heroin-only* overdose visits are more than three times as likely for males than females (13.3/100,000 and 4.2/100,000, respectively) (Table 2). Males are also twice as likely to experience opioid-related mortality as females (6.7/100,000 and 3.0/100,000, respectively). The variation in outcomes within and among the demographic categories illustrates the widespread nature of the opioid epidemic.

The impact of AB 2384 on reducing disparities among racial and ethnic groups, age cohorts, and by gender is unknown because the demographic composition of the 9,979 new MAT medication users and 4,539 new MAT behavioral therapy users (who are not mutually exclusive) is undefined.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact[28] of AB 2384, 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

Utilization Impacts

Long-term utilization of MAT drugs 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 patients suffering from OUD. Due to continuing structural and attitudinal barriers (see the *Background* section), CHBRP does not forecast that the level of MAT users receiving services would increase to more than 25% per year.

As new drugs are approved by the FDA, shifts in utilization could occur. For example, the new injectable 30-day buprenorphine approved in late 2017 could alter the market for buprenorphine administration and increase use of the injectable version over sublingual versions (FDA, 2017).

Cost Impacts

MAT maintenance treatment needs would continue and possibly increase if incidence of OUD increases over time. The constraints on the supply of providers (Clemans-Cope et al., 2018) would limit the level of increase associated with new users, However, new, more expensive brand-name drugs coming to market are required to be covered by AB 2384 without utilization management, which could result in long-term shifts in use towards more expensive options, which would increase per user costs and per unit costs for certain drugs. However, if those drugs are more effective than current MAT drugs, they could come with cost offsets and increased adherence that would limit average cost increases.

Shifts for Medi-Cal

CHBRP anticipates that the prohibition on utilization management will make MAT and brand-name drugs, and therapy associated with MAT relatively easier to access by Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition to the generation of new users in 2019 (users who would not otherwise have engaged in MAT), the lack of utilization management could, in future years, shift some Medi-Cal beneficiaries who would have chosen to access coverage for MAT through Drug Med-Cal to accessing MAT through a Med-Cal managed care plan due to the AB 2384 compliant absence of any utilization management tools.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable

[28] See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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 on social determinants of health, premature death, and economic loss.

The opioid epidemic across the U.S. and in California continues to grow, thus in the foreseeable future, CHBRP anticipates the demand for MAT would 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 insurer utilization management tools would continue to facilitate MAT treatment for some number of enrollees; however, limited patient readiness for treatment and the MAT demand-supply mismatch remain significant barriers to care. The (under) supply of MAT providers may improve in the future as newly funded MAT provider training programs take effect through the California Department of Public Health and Department of Health Care Services (CDPH, 2016) and as California's 58 counties implement the new Drug Medi-Cal Organized Delivery System for Medi-Cal beneficiaries (Joshi et al., 2017).

Impacts on Social Determinants of Health[29]

Periodically, health insurance mandates may influence social determinants of health (SDoH), which can mediate health inequities. Consequences of addiction may include involvement with the criminal justice system and unstable housing or family situations. Krebs et al. (2016) reported that costs associated with drug-related crime were significantly lower in the 6 months following MAT initiation (and unlimited periods of MAT) as compared with short-term detoxification-only program ($17,550 in savings). Savings were largest for heroin users compared to prescription opioid users and savings were larger for males than females. According to the National Health Care for the Homeless Council, addiction can disrupt or prevent stable housing situations for people with OUD. Baggett et al. (2013) estimated that about half the people experiencing homelessness used or abused illicit drugs and were nine times more likely to die from opioid overdose than those with stable housing. Furthermore, 81% of overdose deaths in this study's homeless population were attributable to opioids as compared with the national rate of 61%.

Disruption of the family unit and poor child health outcomes are two other consequence of addiction that have significant long-term effects on SDoH including education, employment, and income potential. Although California has one of the lowest rates of prenatal alcohol or illicit drug exposure, hospital discharge claims data show, between 2008 and 2015, a 95% increase in newborns affected by drugs (1,862 and 3,633, respectively) (CCWCP, 2017). This statistic includes neonatal abstinence syndrome (NAS) where newborns experience withdrawal symptoms. Klaman et al. (2017) performed a literature review to inform national guidelines for treating pregnant mothers with OUD. Research showed that untreated pregnant women had an elevated risk of low–birthweight newborns, intrauterine growth restrictions and placental changes as compared with pregnant mothers in MAT. Recognizing the need for treatment for pregnant women with OUD, the California Department of Public Health created a taskforce to address the need for MAT among women of childbearing age and early OUD screening during pregnancy (CDPH, 2016). Reducing the incidence of neonatal abstinence syndrome (NAS) would result in immediate reduction of hospital stays (16.9 hospital days for NAS newborns vs. 2.1 for non-exposed newborns) (CCWCP, 2017). Additionally, early screening and treatment could improve rates of family unit maintenance or reunification, ultimately avoiding the documented negative behavioral, physical and emotional outcomes of children placed in substitute care settings. California Child Welfare Services reported that 58% of parents/guardians with open cases undergoing a needs assessment required substance abuse treatment (which includes OUD) (NCCD, 2016). Taken as a whole, (treatment of) OUD is inextricably linked bidirectionally with many important social determinants of health.

[29] For more information about SDoH, see CHBRP's publication *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses* at http://www.chbrp.org/analysis_methodology/docs/Incorporating Relevant Social_Determinants of Health in CHBRP Analyses Final to WEBSITE 033016.pdf.

The impact of AB 2384 on SDoH is unknown: however, it stands to reason that, on an individual basis, people with OUD who are adherent to MAT could see reduced interactions with the criminal justice system and/or improvements in family and housing stability.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death occurring before the age of 75 years (Cox, 2006).[30] In California, the Department of Public Health estimates that there are nearly 102,000 premature deaths each year, accounting for about 1.9 million years of potential life lost (YPLL) (CDPH, 2011). 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). The CDC described the increase in premature mortality as occurring in three waves: (1) 1990s: increased prescribing of opioids led to more overdose deaths in the late 1990s; (2) 2010: increased substitution of prescription opioids with heroin, a cheaper alternative sometimes easier to obtain; and (3) 2013: significant increase in overdose deaths associated with illicitly manufactured synthetic opioids (fentanyl). This last wave is particularly harmful because opioid users are unaware of variations in strength for every dose purchased; fentanyl appears to remain a significant problem in 2018 (CDC, 2017).

After 25 years of increasing life expectancy in the U.S., researchers from the National Center for Health Statistics reported that life expectancy fell from 78.9 years in 2014 to 78.6 years in 2016 (Kochanek et al., 2016). At the population level, this translates to a significant loss that researchers are linking in part to the opioid-related deaths (Dowell et al., 2017). The age cohorts most significantly affected by this change in life expectancy are age groups 15 to 24 years (7.8%), 25 to 34 years (10.5%), and 35 to 44 years (6.7%), which correlates with the age cohorts with the highest rates of OUD overdose and mortality (Kochanek et al., 2016; Rudd et al., 2016).

The most recent (national) data CHBRP found regarding YPLL associated with opioid overdose comes from the CDC, which estimated 830,652 YPLL for those under age 65 in 2008 (CDC, 2011). For context, this is similar to the YPLL associated with motor vehicle crashes in the same year. Research by Ruhm et al. (2017) may explain part of the challenge of accurately assessing mortality and YPLL. They compared death-certificate-reported rates and corrected-opioid-fatality rates using imputed drug involvement and concluded that mortality was underreported by 25% in California in 2014 (corrected rate: 6.9/100,000 Californians vs. reported rate: 5.2/100,000).

The long-term impact of AB 2384 on premature death is unknown; however, it stands to reason that, for some enrollees who obtain MAT, there will be a reduction in premature deaths due to opioid overdose. CHBRP does not anticipate this would produce a change in the statewide opioid mortality rate, however. CHBRP found no recent literature addressing economic loss and OUD.

[30] 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") (Cox, 2006). For more information about CHBRP's public health methodology, see: http://www.chbrp.org/analysis_methodology/docs/Public%20Health%20Approach%20Final%20091216.pdf.

APPENDIX A TEXT OF BILL ANALYZED

On February 15, 2018, the California Assembly Committee on Health requested that CHBRP analyze AB 2384.

ASSEMBLY BILL No. 2384

Introduced by Assembly Member Arambula

February 14, 2018

An act to add Section 1367.207 to the Health and Safety Code, and to add Section 10123.204 to the Insurance Code, relating to medication-assisted treatment.

legislative counsel's digest

AB 2384, as introduced, Arambula. Medication-assisted treatment. Existing law, the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene), 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. Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services, 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.

Existing law requires the State Department of Health Care Services to license narcotic treatment programs to use narcotic replacement therapy in the treatment of addicted persons. Existing law specifies certain drugs, including methadone and buprenorphine, that are authorized for use in narcotic replacement therapy and medication-assisted treatment by licensed narcotic treatment programs. Existing law establishes the Drug Medi-Cal Treatment Program, under which the department is authorized to enter into contracts with each county for the provision of various alcohol and drug treatment services,

including substance use disorder services, narcotic treatment program services, naltrexone services, and outpatient drug-free services, to Medi-Cal beneficiaries.

This bill would require a drug formulary maintained by a health care service plan, including a Medi-Cal managed plan, or health insurer to include, at a minimum, specified prescription drugs for the medication-assisted treatment, as defined, of substance abuse disorders. The bill would provide that medication-assisted treatment is presumed to be medically necessary, and is not subject to specified requirements of a health care service plan or policy of health insurance, including prior authorization and an annual or lifetime dollar limit. Because a willful violation of the bill's requirements relative to health care service plans 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.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1367.207 is added to the Health and Safety Code, to read:

1367.207. (a) A health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall include, at a minimum, the following medication-assisted treatment prescription drugs for substance abuse disorders:

(1) Buprenorphine.

(2) Methadone.

(3) Naloxone.

(4) Extended-release injectable naltrexone.

(5) A combination of buprenorphine and naloxone.

(6) New formulations and medications as they are approved by the United States Food and Drug Administration (FDA) for the treatment of substance abuse disorders.

(b) Medication-assisted treatment provided pursuant to this section is presumed to be medically necessary and is not subject to the following:

(1) Prior authorization.

(2) An annual or lifetime dollar limit.

(3) A limitation to a predesignated facility, a specific number of visits, days of coverage, scope or duration of treatment, or other similar limitations.

(4) Financial requirements different than those for other illnesses covered under the health care service plan.

(5) Step therapy, fail first policies, or other similar drug utilization strategies or policies for patients that may conflict with a prescribed course of treatment from a licensed health care professional.

(c) The requirements of this section shall not be subject to an insured's prior success or failure with the medication-assisted treatment services provided.

(d) For purposes of this section, the following definitions apply:

(1) "Medication-assisted treatment" means the use of medications, commonly in combination with counseling and behavioral therapy, to provide a comprehensive approach to the treatment of substance abuse disorders. Medication-assisted treatment includes, but is not limited to, pharmacologic and behavioral therapies.

(2) "Pharmacologic therapy" means a prescribed course of treatment that may include methadone, buprenorphine, naltrexone, or other FDA-approved or evidence-based medications for the treatment of substance abuse disorders.

(3) "Behavioral therapy" means an individual, family, or group therapy designed to help a patient engage in the treatment process, modify a patient's attitude and behaviors related to substance abuse disorders, and increase healthy life skills.

(4) "Medically necessary" means a service that is reasonable and necessary to protect life, prevent significant illness or significant disability, or to alleviate severe pain, as determined by a treating licensed health care professional in consultation with the patient.

(5) "Financial requirements" means a deductible, copayment, coinsurance, or out-of-pocket maximum.

(e) For purposes of this section, “health care service plan” includes Medi-Cal managed care plans that contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

SEC. 2. Section 10123.204 is added to the Insurance Code, to read:

10123.204. (a) A health insurer that provides prescription drug benefits and maintains one or more drug formularies shall include, at a minimum, the following medication-assisted treatment prescription drugs for substance abuse disorders:

(1) Buprenorphine.

(2) Methadone.

(3) Naloxone.

(4) Extended-release injectable naltrexone.

(5) A combination of buprenorphine and naloxone.

(6) New formulations and medications as they are approved by the United States Food and Drug Administration (FDA) for the treatment of substance abuse disorders.

(b) Medication-assisted treatment provided pursuant to this section is presumed to be medically necessary and is not subject to the following:

(1) Prior authorization.

(2) An annual or lifetime dollar limit.

(3) A limitation to a predesignated facility, a specific number of visits, days of coverage, scope or duration of treatment, or other similar limitations.

(4) Financial requirements different than those for other illnesses covered under the policy of health insurance.

(5) Step therapy, fail first policies, or other similar drug utilization strategies or policies for patients that may conflict with a prescribed course of treatment from a licensed health care professional.

(c) The requirements of this section shall not be subject to an enrollee’s prior success or failure with the medication-assisted treatment services provided.

(d) For purposes of this section, the following definitions apply:

(1) “Medication-assisted treatment” means the use of medications, commonly in combination with counseling and

behavioral therapy, to provide a comprehensive approach to the treatment of substance abuse disorders. Medication-assisted treatment includes, but is not limited to, pharmacologic and behavioral therapies.

(2) “Pharmacologic therapy” means a prescribed course of treatment that may include methadone, buprenorphine, naltrexone, or other FDA-approved or evidence-based medications for the treatment of substance abuse disorders.

(3) “Behavioral therapy” means an individual, family, or group therapy designed to help a patient engage in the treatment process, modify a patient’s attitude and behaviors related to substance abuse disorders, and increase healthy life skills.

(4) “Medically necessary” means a service that is reasonable and necessary to protect life, prevent significant illness or significant disability, or to alleviate severe pain, as determined by a treating licensed health care professional in consultation with the patient.

(5) “Financial requirements” means a deductible, copayment, coinsurance, or out-of-pocket maximum.

SEC. 3. 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.

APPENDIX B LITERATURE REVIEW METHODS

This appendix describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the effects of medication-assisted treatment (MAT) for opioid use disorder (OUD) were identified through searches of PubMed, the Cochrane Library, EMBASE, Scopus, and PsycINFO. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality (AHRQ), Scottish Intercollegiate Guideline Network, International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, and the National Institute for Health and Care Excellence (NICE).

The search was limited to abstracts of studies published in English.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

The search was limited to studies published from 2007 to present. Of the 1,262 articles found in the literature review, 45 were reviewed for potential inclusion in this report on AB 2384, and a total of 28 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they were of poor quality, did not report findings from clinical research studies, or did not address use of maintenance MAT medications to treat OUD.

Medications used for long-term, maintenance treatment of OUD are also used on a short-term basis to manage symptoms of withdrawal from opioids. CHBRP did not review literature on the effectiveness of these medications for withdrawal management because AB 2384 refers to their use for MAT, which is defined as long-term maintenance treatment to prevent relapse.

CHBRP also did not review literature on the effectiveness of transdermal formulations of buprenorphine because the FDA has only approved transdermal buprenorphine for the treatment of chronic pain and not for treatment of OUD.

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach.*[31] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and

[31] Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence; and*
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms

Bupreorphine

Buprenorphine plus naloxone

Drug abuse

Medication assisted therapy

Medication assisted treatment

Methadone

Naloxone

Naltrexone

Narcotic dependence

Opiate substitution treatment

Opiates

Opioid-related disorders/therapy

Opioid treatment

Opioids

Prior authorization

Step therapy

Utilization management

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm PricewaterhouseCoopers (PwC).[32]

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.[33]

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

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions specifically relevant to the coverage requirement for medication-assisted treatment (MAT) for the treatment of substance use disorder (SUD) per AB 2384. For the purposes of this analysis, the impact of AB 2384 is assumed to be limited to opioid use disorder (OUD).

A number of core assumptions are mentioned in the *Benefit Coverage, Utilization, and Cost Impacts* section of the report.

Following are descriptions of methodology and additional assumptions used to develop the estimates of cost impacts:

- MAT prescription drugs used National Drug Codes (NDC) codes and the injectable MAT drug procedure codes identified with using the Truven Health Analytics Red Book™ and reviewed by a content expert. Additionally, the MAT drug list carved out the pain management medication and only focus on the medication for OUD based on a content expert's review.

Table 10. MAT Drugs for OUD and Overdose Reversal Drugs

Category	Drug	Drug Product Name	Route Name
Maintenance	Buprenorphine	Buprenorphine	Sublingual
Maintenance	Buprenorphine	Buprenorphine Hcl	Sublingual
Maintenance	Buprenorphine	Buprenorphine Hydrochloride	Oral
Maintenance	Buprenorphine	Buprenorphine Hydrochloride	Sublingual
Maintenance	Buprenorphine	Buprenorphine Hydrochloride Sublingual	Sublingual

[32] CHBRP's authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[33] See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Category	Drug	Drug Product Name	Route Name
Maintenance	Buprenorphine	Probuphine	Subcutaneous
Maintenance	Combination Buprenorphine-Naloxone	Bunavail	Buccal
Maintenance	Combination Buprenorphine-Naloxone	Buprenorphine And Naloxone	Sublingual
Maintenance	Combination Buprenorphine-Naloxone	Buprenorphine Hcl And Naloxone Hcl	Sublingual
Maintenance	Combination Buprenorphine-Naloxone	Buprenorphine Hydrochloride And Naloxone Hydrochloride Dihydrate	Sublingual
Maintenance	Combination Buprenorphine-Naloxone	Suboxone	Oral
Maintenance	Combination Buprenorphine-Naloxone	Suboxone	Sublingual
Maintenance	Combination Buprenorphine-Naloxone	Zubsolv	Sublingual
Maintenance	Naltrexone	Naltrexone Hydrochloride	Oral
Maintenance	Naltrexone	Vivitrol	
Emergency	Naloxone	Evzio	Intramuscular; Subcutaneous
Emergency	Naloxone	Naloxone Hydrochloride	Intramuscular; Intravenous; Subcutaneous
Emergency	Naloxone	Naloxone Hydrochloride	Parenteral
Emergency	Naloxone	Narcan	Nasal

Source: California Health Benefits Review Program, 2018.

Table 11. HCPCS Codes Used for Outpatient MAT Drugs and Overdose Reversal Drugs

Category	Drug	HCPC
Maintenance	Buprenorphine	J0592
Maintenance	Combination Buprenorphine-Naloxone	J0571
Maintenance	Combination Buprenorphine-Naloxone	J0572
Maintenance	Combination Buprenorphine-Naloxone	J0573
Maintenance	Combination Buprenorphine-Naloxone	J0574

Category	Drug	HCPC
Maintenance	Combination Buprenorphine-Naloxone	J0575
Maintenance	Naltrexone	J2212
Maintenance	Naltrexone	J2315
Emergency	Naloxone	J2310

Source: California Health Benefits Review Program, 2018.

The following tables list the HCPCS and CPT codes used to identify the behavioral therapy services for substance abuse.

Table 12. CPT/HCPCS Codes Used for Behavioral Therapy Services for Substance Abuse

CPT/HCPCS Code	Description
H0001-H0004 H0013-H0014 H0020-H0030	Drug, Alcohol, and Behavioral Health Services
H0031-H0034 H0036-H0040	Mental Health Programs and Medication Administration Training
H0045-H0046 H0048-H0050	Miscellaneous Drug and Alcohol Services
H2000-H2035,H2037	Other Mental Health and Community Support Services
90785,90791,90792,90832,90833, 90834,90836,90837,90838,90839, 90840,90846,90846,90847,90849, 90853,90882,90882,90887	Psychotherapy

Source: California Health Benefits Review Program, 2018.

CHBRP used the Opioid Use Disorder diagnosis codes to identify the Opioid Use Disorder users in the 2016 MarketScan® Commercial Claims and Encounters Database.

Table 13. Diagnosis Codes Used for Opioid Use Disorder

Diagnosis Code (ICD 9 and ICD-10)	Description
304.00-305.52	Opioid Use Disorder
F11.10-F11.99	Opioid Use Disorder

Source: California Health Benefits Review Program, 2018.

Based on that list of unique individuals, CHBRP identified all individuals with OUD diagnosis codes throughout the year. CHBRP flagged those claims matching the NDC codes and HCPCS codes in the

MAT drug table above to identify those who had or had no MAT treatment and behavioral therapy services (Table 14).

Table 14. MarketScan MAT Cohorts

MarketScan Grouping
MAT Users with OUD and Behavioral Health
MAT Users with OUD and without Behavioral Health
MAT Users without OUD but with Behavioral Health
MAT Users without OUD and Behavioral Health

Source: California Health Benefits Review Program, 2018.

Baseline MAT unit costs were trended at an annual rate 0.8% per year from 2016 to 2019 (Express Scripts, 2018). The 0.8% trend represents the 2017 MAT drug trends for the commercial population represented within the report. The analysis assume that the unit cost per script does not change postmandate.

Based on 2017 Mental Health and Substance Abuse Treatment Trends analysis performed by Truven Health Analytics (Health Leaders Media, 2017), baseline behavioral therapy services unit cost were trended at an annual rate 10% per year from 2016 to 2019. The analysis assumed that utilization rates per 1,000 enrollees change postmandate due to the removal of utilization management. Baseline utilization rates per 1,000 were developed based on MarketScan® data for members who use the MAT drugs.

CHBRP's carrier surveys were used to estimate the percentage of enrollees who had outpatient prescription drug (OPD) coverage for MAT drugs, overdose reversal drugs, and behavioral therapy services. Results indicate that almost all enrollees have on-formulary coverage for the listed drugs and behavioral therapy services – but no enrollees had benefit coverage entirely free of the utilization management tools AB 2384 would prohibit (see Tables 4, 5, and 6). The removal of these barriers is expected to increase utilization of MAT by approximately 25%.

Postmandate Offset Services – Inpatient, Outpatient, and Professional

There are likely to be changes in the utilization of non-MAT services as a result of receiving MAT treatment. Mohlman et al. (2016) indicated reductions in inpatient, emergency, medical specialist, and imaging services and increases in PCP visits and surgical specialist visits. To estimate the value of changes in utilization, CHBRP relied on the estimated difference in utilization from Mohlman between MAT and non-MAT OUD populations.

- 48.67% reduction in inpatient days
- 42.3% reduction in inpatient discharges
- 41.9% reduction in ED visits
- 55.66% increase in PCP visits
- 46.58% reduction in all imaging services
- 50% reduction in colonoscopy

- 13.2% reduction in medical specialist visits
- 60.85% increase in surgical specialist visits

There are no side effects or harms associated with increased use of MAT that could lead to measurable increased health service use or spending. The Mohlman et al. (2016) study included data on utilization offsets that would have included additional office visits or services that may have resulted from both minimal side effects (i.e., redness or swelling at injection sites) and larger harms, like increased risk of overdose when patients treated with naltrexone who discontinue treatment may be sensitive to lower doses of opioids, which could increase their risk of overdose (SAMHSA, 2015). In general, the utilization and cost offsets calculated in this report take into consideration added health services use and spending, regardless of whether it is associated with the direct cost of the treatment or additional services associated with side effects. Please see *Medical Effectiveness* section for literature on other harms.

Unit costs were estimated using a combination of the Mohlman estimates, MarketScan data, and relationships between commercial and Medi-Cal unit costs. For Inpatient Days and ED visits, CHBRP used the Mohlman paper to set the Medi-Cal unit cost (cost per day/visit) since their reported costs were for a Medicaid population and reflected an appropriate mix of IP services. The Commercial Inpatient Days and ED Visits unit cost was calculated from the Medicaid unit cost by dividing by 40%. The other services unit Medi-Cal unit costs were estimated by using the existing difference between MarketScan Data and Medi-Cal data.

Table 15. Offset assumptions

	Average Utilization Change (Mohlman) per MAT User	Commercial Unit Cost	Medi-Cal Unit Cost
Inpatient Days	-1.46	$3,300	$1,300
ED Visits	-1.04	$600	$240
PCP Visits	5.46	$150	$60
Imaging Services	-0.67	$375	$150
Medical Specialist Visits	-0.33	$155	$65
Surgical Specialist Visits	1.15	$590	$235

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 2384 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

APPENDIX D OUTPATIENT PRESCRIPTION DRUG BENEFITS AND STATE-LEVEL MANDATES

As noted in Table 16, for 2019, CHBRP estimates that approximately 1.4% of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI) have no coverage for outpatient prescription drugs (OPDs) and 3.0% of these enrollees have OPD coverage that is not regulated by DMHC or CDI.

Table 16. 2019 Outpatient Prescription Drug Coverage

	Enrollees in DMHC-Regulated Plans and in CDI-Regulated Policies
	Total
Enrollee Counts	
Total enrollees in plans/policies subject to state mandates[(a)]	23,433,000
Outpatient Prescription Drug (OPD) Coverage	
DMHC- or CDI-regulated brand name and generic OPD coverage	95.5%
DMHC or CDI regulated generic only coverage	0.1%
No OPD coverage	1.4%
Other OPD coverage	3.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organization; OPD = Outpatient Prescription Drug.

Additional detail about the presence and absence of OPD coverage in various market segments is presented below, in Table 17, Table 18, and Table 19.

Relevant State and Federal Law

A number of overlapping state and federal laws require broad OPD coverage or coverage for particular drugs, but the requirements are not applicable to all forms of health insurance.

Some (but not all) small-group and individual market health care service plans and health insurance policies are required to provide coverage for OPDs as part of coverage for Essential Health Benefits (EHBs).[34]

Some (but not all) large-group, small-group, and individual market health care service plans and health insurance policies are required to provide coverage for particular drugs as part of preventive services, but not for all OPDs.[35]

Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require coverage for particular drugs. For example, there is a mandate that requires coverage for insulin and prescription drugs for the treatment of diabetes but does not require coverage for drugs that treat diabetes-related conditions.[36]

However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have an OPD benefit.

Presence or Absence of Coverage for Outpatient Prescription Drugs and Related Regulation

Coverage of OPDs was estimated through surveys and queries. For enrollees in the privately funded markets regulated by DMHC and CDI, coverage was determined by responses to a survey of the largest providers of health insurance in California. Responses to this survey represent 95% of enrollees in these markets. The California Public Employees' Retirement System (CalPERS) was queried regarding coverage among DMHC-regulated plan enrollees associated with CalPERS. The California Department of Health Care Services (DHCS) was queried about coverage among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

From this information, CHBRP concluded that most enrollees have coverage for OPDs through their DMHC-regulated plan or CDI-regulated policy. OPD coverage is generally accessed through the enrollee's "pharmacy benefit," and generally used when acquiring drugs at an outpatient pharmacy or mail order service. When OPD coverage is handled through a subcontracting pharmacy benefit management (PBM) organization, the plan or policy, licensed by DMHC or CDI, requires the subcontracting PBM to comply with relevant state-level health insurance benefit mandates.

As coverage for OPDs is not universally required; some enrollees in DMHC-regulated plans and CDI-regulated policies have no OPD coverage. Although their health insurance covers prescription drugs delivered during a hospital (or other facility) admission and some prescription drugs that are dispensed through a clinician's office, it would not generally help them acquire drugs intended for outpatient use. As noted above, there are some drug specific exceptions, such as insulin, but coverage would be limited to those specific outpatient drugs.

In terms of alternate regulation, some enrollees who have no OPD benefit through their DMHC-regulated plan or CDI-regulated policy still do have an OPD benefit — but have it through another source, one that is not regulated by DMHC or CDI. Such a circumstance can occur if, for example, an employer arranges for a large-group plan to exclude coverage for OPDs and then contracts separately with a PBM to

[34] California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA
[35] California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA
[36] California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61

administer an OPD benefit. In this example, the PBM is not a subcontractor to a plan or insurer; it is directly contracting with the employer. If the contracting PBM is not licensed by either DMHC or CDI, it is not subject to state-level health insurance benefit mandates.

Table 17. 2019 Outpatient Prescription Drug Coverage in the Large Group and Publicly Funded Markets

	DMHC-Regulated Plans					CDI-Regulated Policies	
	Privately Funded Large Group		Publicly Funded Plans			Privately Funded Large Group	
	Grand-fathered	*Non-Grand-fathered*	*CalPERS HMOs*[a]	*MCMC (Under 65)*[b]	*MCMC (65+)*[b]	*Grandfathered*	*Non-Grand-fathered*
Enrollee Counts							
Total enrollees in plans/policies subject to state mandates[c]	1,860,000	7,511,000	887,000	6,832,000	678,000	5,000	209,000
Outpatient Prescription Drug (OPD) Coverage							
DMHC- or CDI-regulated brand name and generic OPD coverage	95.9%	90.5%	79.5%	100.0%	100.0%	80.3%	86.8%
DMHC- or CDI-regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No OPD coverage	3.8%	3.0%	0.0%	0.0%	0.0%	14.9%	2.2%
Other OPD coverage	0.3%	6.5%	20.5%	0.0%	0.0%	4.8%	11.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) As of September 2017, 56% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2019.

(b) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

Table 18. 2019 Outpatient Prescription Drug Coverage in the DMHC-regulated Small Group and Individual Markets

	Privately Funded Small Group				Privately Funded Individual			
	Grand-fathered	*Non-Grand-fathered Covered California(a)*	*Non-Grand-fathered Mirror Plans (b)*	*Other Non-Grand-fathered*	*Grand-fathered*	*Non-Grand-fathered Covered California(a)*	*Non-Grand-fathered Mirror Plans (b)*	*Other Non-Grand-fathered*
Enrollee Counts								
Total enrollees in plans/policies subject to state mandates[c]	355,000	49,000	687,000	2,026,000	103,000	1,157,000	611,000	210,000
Outpatient Prescription Drug (OPD) Coverage								
DMHC-regulated brand name and generic OPD coverage	99.9%	100.0%	100.0%	100.0%	90.7%	100.0%	100.0%	100.0%
DMHC-regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No OPD coverage	0.0%	0.0%	0.0%	0.0%	9.3%	0.0%	0.0%	0.0%
Other OPD coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

Table 19. 2019 Outpatient Prescription Drug Coverage in CDI-regulated Small Group and Individual Markets

	Privately Funded Small Group				Privately Funded Individual			
	Grand-fathered	*Non-Grand-fathered Covered California (a)*	*Non-Grand-fathered Mirror Plans (b)*	*Other Non-Grand-fathered*	*Grand-fathered*	*Non-Grand-fathered Covered California (a)*	*Non-Grand-fathered Mirror Plans (b)*	*Other Non-Grand-fathered*
Enrollee Counts								
Total enrollees in plans/policies subject to state Mandate[(c)]	1,000	3,000	23,000	106,000	87,000	2,000	8,000	23,000
Outpatient Prescription Drug (OPD) Coverage								
CDI-regulated brand name and generic OPD coverage	96.5%	100.0%	100.0%	100.0%	50.9%	100.0%	100.0%	100.0%
CDI-regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	39.1%	0.0%	0.0%	0.0%
No OPD coverage	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Other OPD coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2018.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

APPENDIX E INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by the bill author's office in March 2018.

- H. K. Knudsen, A. J. Abraham, and C. B. Oser, "Barriers to the Implementation of Medication-Assisted Treatment for Substance Use Disorders: The Importance of Funding Policies and Medical Infrastructure," Evaluation and Program Planning 34, no. 4 (November 2011): 375-81, doi:10.1016/j.evalprogplan.2011.02.004.
- California Health Care Foundation. "Why Health Plans Should Go to the 'MAT' in the Fight Against Opioid Addiction." September 2017. http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/PDF%20W/PDF%20Why%20Health%20Plans %20Should%20Go%20to%20the%20MAT.pdf
- https://csam-asam.org/sites/default/files/pdf/misc/insurance_barriers_mat_2016_final.pdf
- https://csam-asam.org/sites/default/files/pdf/misc/csam-insurance_benefits_opioids-2016-approved.pdf

In addition, Alkermes, the pharmaceutical company that manufactures Vivitrol (extended-release naltrexone), submitted a letter regarding their product.

Submitted information is available upon request. For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

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** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **PricewaterhouseCoopers**, 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. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego
Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis
Ninez Ponce, PhD, Co-*Vice Chair for Cost*, University of California, Los Angeles
Nadereh Pourat, PhD, Co-*Vice Chair for Cost*, University of California, Los Angeles
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Danielle Casteel, MA, University of California, San Diego
Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton
Shauna Durbin, MPH, University of California, Davis
Margaret Fix, MPH, University of California, San Francisco
Ronald Fong, MD, MPH, University of California, Davis
Brent Fulton, PhD, University of California, Berkeley
Sarah Hiller, MA, University of California, San Diego
Naomi Hillery, MPH, University of California, San Diego
Jeffrey Hoch, PhD, University of California, Davis
Michelle Ko, MD, PhD, University of California, Davis
Gerald Kominski, PhD, University of California, Los Angeles
Elizabeth Magnan, MD, PhD, University of California, Davis
Ying-Ying Meng, PhD, University of California, Los Angeles
Jacqueline Miller, University of California, San Francisco

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Adara Citron, MPH, Principal Policy Analyst
Juan Miramontes, Intern
Erin Shigekawa, MPH, Principal Policy Analyst
Karla Wood, Program Specialist

California Health Benefits Review Program
MC 3116
Berkeley, CA 94720-3116
info@chbrp.org
www.chbrp.org
(510) 664-5306

**A small percentage of AJ Scheitler's time is available to serve as a backup CHBRP staff resource.*

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Garen Corbett, MS
Director

Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, (510) 664-5306, info@chbrp.org, or www.chbrp.org