KEY FINDINGS

Analysis of California Senate Bill 626 Perinatal Health Screenings and Treatment

Summary to the 2025-2026 California State Legislature, April 22, 2025

CHBRP

Summary

The version of California Senate Bill (SB) 626 analyzed by California Health Benefits Review Program (CHBRP) would require Department of Managed Health Care (DMHC)–regulated plans and California Department of Insurance (CDI)–regulated policies to cover at least one medication approved by the U.S. Food and Drug Administration (FDA) for perinatal[1] mental health and at least one digital (e.g., app-based) therapeutic approved[2] by the FDA for perinatal mental health. Currently, there is one medication (zuranolone) and one digital therapeutic (MamaLift Plus) with FDA approval for perinatal mental health conditions.

SB 626 would also require that DMHC-regulated plans and CDI-regulated policies provide and report annually on utilization of case management and care coordination during the perinatal period. Finally, SB 626 would require that a licensed health care provider who provides perinatal care for a patient must screen, diagnose, and treat the patient for a perinatal mental health condition according to the clinical guidelines from the American College of Obstetricians and Gynecologists (ACOG).

In 2026, 24.1 million Californians (63% of all Californians) enrolled in state-regulated health insurance would have insurance subject to SB 626.

Benefit Coverage

Benefit coverage for zuranolone would increase from 3% to 54% postmandate. Benefit coverage for MamaLift Plus would increase from 2% to 100% postmandate. SB 626 would not exceed essential health benefits (EHBs).

Medical Effectiveness

Overall, the findings on treatments for perinatal mental health vary. While there is *some evidence* that the FDA-approved medication for perinatal mental health is effective, *not enough research* has been conducted to determine the effect of the digital therapeutic, *not enough research* has been conducted to determine whether screening for perinatal depression improves health outcomes, and there is *conflicting evidence* that care coordination and case management are effective in improving health outcomes.

Cost and Health Impacts[3]

In 2026, CHBRP estimates that SB 626 would result in 328 additional people taking zuranolone and an additional 5,402 people using MamaLift Plus. While CHBRP does not anticipate new people gaining coverage for perinatal mental health screening, CHBRP does estimate an additional 37,581 perinatal mental health screenings.

SB 626 would increase total expenditures by $9,842,000 (0.01%).

Context

Perinatal mental health conditions can include depression, postpartum psychosis, anxiety disorders, bipolar disorder, posttraumatic stress disorder (PTSD), and obsessive-compulsive disorder (OCD)[4]. Medication use for mental health conditions during pregnancy is common practice. However, there is limited data on the use of medications to treat mental health conditions during pregnancy because studies are limited and tend to exclude pregnant patients. For this reason, there are very few FDA-approved medications for mental health

[1] For the purposes of SB 626, CHBRP has defined the perinatal period as the period including pregnancy plus 12 months after the end of pregnancy.
[2] While SB 626 specifies digital therapeutics with FDA approval, CHBRP has assumed a broad interpretation of being "approved by the FDA" to include devices classified as either FDA-cleared or FDA-approved. See *Analytic Approach and Assumptions* in the full report for detail.

[3] Similar cost and health impacts could be expected for the following year though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.
[4]Although definitions vary regarding whether perinatal mental health conditions can include conditions that begin before pregnancy, SB 626 specifies its applicability to perinatal mental health conditions that occur during pregnancy, the postpartum period, or the perinatal period. ACOG

conditions specifically indicated for use by pregnant people, although that does not mean that pregnant patients go through their pregnancy without treatment.

Currently, there is one medication with FDA approval and one digital therapeutic with FDA approval for perinatal mental health conditions. Both are indicated specifically for postpartum depression (PPD). In 2023, the FDA approved zuranolone (Zurzuvae), an oral medication used to treat PPD. MamaLift Plus, an FDA-approved digital therapeutic, is an 8-week app-based program for patients aged 22 and older with mild-to-moderate PPD. A prescription is required to access the platform, which includes self-paced "therapy sessions," exercises, meditations, and the option of requesting a "therapist consultant" when needed.[5]

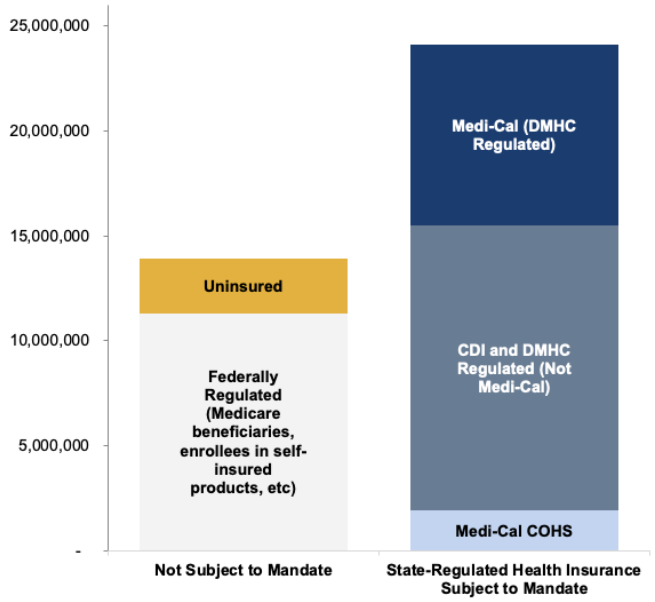
Bill Summary

SB 626 would require DMHC-regulated plans and CDI-regulated policies to cover at least one medication approved by the U.S. Food and Drug Administration (FDA) for perinatal mental health and at least one digital therapeutic approved by the FDA for perinatal mental health.

Additionally, SB 626 would require that DMHC-regulated plans and CDI-regulated policies provide case management and care coordination during the perinatal period; that they annually report to the Department of Health Care Services (DHCS) on the utilization and outcomes of case management; and that they publicly post the information reported.

Finally, SB 626 would require that a licensed health care provider who provides perinatal care for a patient must screen, diagnose, and treat the patient for a perinatal mental health condition according to the clinical guidelines from the American College of Obstetricians and Gynecologists (ACOG). SB 626 would change existing screening guidance — at least once during pregnancy, at least once during the first 6 weeks of the postpartum period, and additional postpartum screenings, if determined to be medically necessary and clinically appropriate in the judgment of the treating provider — to follow ACOG clinical guidelines, which recommend that screening for perinatal depression and anxiety occur at the initial prenatal visit, later in pregnancy, and at postpartum visits.

Figure A. Health Insurance in CA and SB 626



Source: California Health Benefits Review Program, 2025.
Note: CHBRP generally assumes alignment of Medi-Cal managed care plan benefits, with limited exceptions.[6]
Key: CDI = California Department of Insurance; COHS = County Organized Health System; DHCS = Department of Health Care Services; DMHC = Department of Managed Health Care.

Impacts

Benefit Coverage

CHBRP estimates that at baseline, 24,116,000 Californians (63%) with state-regulated insurance subject to the mandate are enrolled in plans or policies impacted by SB 626. With regards to the care coordination and case management provision of the bill, 100% of enrollees are in plans and policies that are compliant. With regards to the coverage of zuranolone, 3% of enrollees are in plans and policies that are compliant; with regards to MamaLift Plus, 2% of

specifically recommends screening for depression, anxiety, and bipolar disorder during the perinatal period.
[5] Refer to CHBRP's full report for full citations and references.
[6] Although COHS plans are not subject to the Knox-Keene Act, DHCS generally updates Medi-Cal managed care plan contracts, All Plan Letters, and other appropriate authorities for alignment of managed care plan benefits, except in cases when the benefit is carved out of the Medi-Cal managed care plan contract or the law exempts specified Medi-Cal contracted providers.

enrollees are in plans and policies that are compliant at baseline.

Utilization

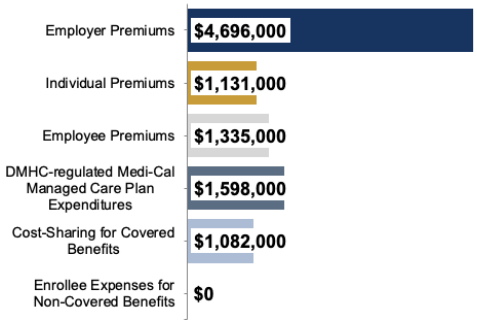
Postmandate, CHBRP estimates that the number of people who use zuranolone with coverage would grow to 345 enrollees and that the number of people who use MamaLift Plus with coverage would grow to 5,402 enrollees. CHBRP estimates an additional 37,581 perinatal mental health screenings postmandate.

Expenditures

For DMHC-regulated plans and CDI-regulated policies, SB 626 would increase total expenditures by $9,842,000 (0.01%). Increases in enrollee expenditures at the per member per month (PMPM) level range from $0.014 for Medi-Cal managed care plans, including COHS, to $0.056 for DMHC-regulated individual plans.

CHBRP assumes a cost offset of $112 per treatment course of zuranolone to account for reductions in other healthcare utilization.

Figure B. Expenditure Impacts of SB 626



Source: California Health Benefits Review Program, 2025.
Key: DMHC = Department of Managed Health Care.

Commercial

Changes in premiums as a result of SB 626 would be 0.01% or less for the different types of plans by market segment and ranges from $0.013 for small-group CDI-regulated policies to $0.047 for large-group DMHC-regulated plans.

Medi-Cal

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there would be a 0.005% increase in premiums, which translates to a $0.014 increase PMPM (reflecting the changes in coverage of MamaLift Plus, which is assumed to be covered as a medical benefit).

CalPERS

For enrollees associated with the California Public Employees' Retirement System (CalPERS) in DMHC-regulated plans, there would be a 0.004% increase in premiums, which translates to a $0.033 increase PMPM.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 626.

Medical Effectiveness

Overall, the findings on treatments for perinatal mental health vary. While there is *some evidence*[7] that the FDA-approved medication for perinatal mental health is effective, *not enough research*[8] has been conducted to determine the effect of the digital therapeutic, *not enough research* has been conducted to determine whether screening for perinatal depression improves health outcomes, and there is *conflicting evidence*[9] that care coordination and case management are effective in improving health outcomes.

There is *some evidence* that zuranolone is effective for improving depression for patients with severe PPD in which onset begins within the 3rd trimester of pregnancy or the first 4 weeks postpartum, based on two well-designed randomized controlled trials. Because there are only two industry-funded studies with relatively small sample sizes and limited follow-up, it is unclear how

[7] *Some evidence* indicates that a small number of studies have limited generalizability to the population of interest and/or the studies have a serious methodological concern in research design or implementation. Conclusions could be altered with additional evidence.
[8] *Not enough research* indicates that there are no studies of the treatment, or the available studies are not of high quality, meaning there is not enough evidence available to know whether or not a treatment is effective. It does not indicate that a treatment is not effective.
[9] *Conflicting evidence* indicates that a similar number of studies of equal quality suggest the treatment is effective as suggest the treatment is not effective.

generalizable the effects would be for the entire postpartum population that would be covered by SB 626.

Not enough research has been conducted to determine whether zuranolone is more effective than the selective serotonin reuptake inhibitors (SSRIs) that are currently prescribed for improving health outcomes in women with perinatal depression because there are no studies that compare the two medications. *Not enough research* indicates that there are no studies of the treatment or the available studies are not of high quality, meaning that there is not enough evidence available to know whether or not a treatment is effective. It does not indicate that a treatment is not effective.

Not enough research has been conducted to determine if the digital therapeutic MamaLift Plus is effective at improving depression for people with mild-to-moderate PPD because there are no studies that meet CHBRP's quality standards. *Not enough research* indicates that there are no studies of the treatment or the available studies are not of high quality, meaning that there is not enough evidence available to know whether or not a treatment is effective. It does not indicate that a treatment is not effective.

Not enough research has been conducted to determine whether screening for perinatal depression improves health outcomes. CHBRP did not identify any trials comparing the effects of usual care versus screening plus usual care on health outcomes.

There is *conflicting evidence* that care coordination and case management improve health outcomes, including improvements in depressive scores and breastfeeding initiation and continuation, based on five studies. One study showed that engagement in a collaborative care program increased initiation and continuation of breastfeeding at 6 weeks follow-up. However, evidence is limited by a lack of studies that examine case management and care coordination in a clinical setting with control groups. Because case management and care coordination are not defined in SB 626, it is difficult to generalize these outcomes to the legislation.

Public Health

Given the evidence of medical effectiveness of existing treatments and screening as well as the estimated cost impacts of SB 626, CHBRP concludes that passage of SB 626 would have no short-term public health impact at the state level. At the person-level, enrollees with severe PPD for which psychotherapy and/or SSRIs or serotonin-norepinephrine reuptake inhibitors (SNRIs) are not sufficient may find a reduction in depression symptoms with zuranolone.

Long-Term Impacts

Over time, the utilization of both zuranolone and MamaLift Plus may increase as awareness, provider familiarity, and patient adoption grow. The long-term cost implications of SB 626 may be influenced by market dynamics, technological advancements, and evolving coverage policies. While initial costs may be high due to the novel nature of zuranolone and the relatively new market for prescription digital therapeutics like MamaLift Plus, competition and innovation could drive costs downward. As more pharmaceutical and digital health companies enter the market, the introduction of alternative treatments and expanded research may contribute to pricing pressures that reduce costs. Additionally, as the prescription digital therapeutics sector continues to grow, industry standards and guidance from regulatory and payer bodies may lead to more structured reimbursement frameworks, increasing affordability and accessibility. These factors could moderate the long-term cost impact of SB 626 while supporting broader adoption of both pharmacologic and digital interventions for PPD.

Essential Health Benefits and the Affordable Care Act

SB 626 would not exceed the definition of EHBs in California because SB 626 would expand existing benefit coverage and does not create a new coverage requirement.