KEY FINDINGS

Analysis of California Assembly Bill 3059 Human Milk

Summary to the 2023-2024 California State Legislature, April 16 2024

CHBRP

Summary

California Assembly Bill (AB) 3059 would require health plans regulated by the Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI) to provide coverage for human milk and human milk derivatives. AB 3059 would also exempt general acute care hospitals from the requirement to acquire a tissue bank license in order to store or distribute human milk obtained from a mothers' milk bank.

In 2025, all of the 22.3 million Californians enrolled in state-regulated health insurance would have insurance subject to AB 3059, although the insurance of Medi-Cal beneficiaries in DMHC-regulated plans would not be impacted due to full compliance at baseline.

Benefit Coverage

AB 3059 would affect coverage of two health services: donor human milk (DHM) and human milk-derived fortifiers (HMF). At baseline, CHBRP estimates that 39.13% of enrollees with health insurance subject to AB 3059 have coverage for DHM and HMF. Postmandate, CHBRP estimates that 100% of enrollees with health insurance subject to AB 3059 would have coverage for these benefits. AB 3059 would not exceed essential health benefits (EHBs).

Medical Effectiveness

CHBRP found *clear and convincing evidence* that DHM is more effective than preterm formula in the prevention of necrotizing enterocolitis (NEC) and bronchopulmonary dysplasia (BPD) in preterm infants. CHBRP found *limited evidence* that DHM is not as effective as preterm formula for weight gain, and a *preponderance of evidence* that DHM is no more effective than preterm formula for the prevention of late-onset sepsis (LOS) in preterm infants. Additionally, conclusions were *inconclusive* regarding the effectiveness of fortifiers derived from human milk versus bovine milk on outcomes for preterm infants.

Cost and Health Impacts

In 2025, AB 3059 would result in, approximately, an additional $9,668,000 (0.00006%) in total net annual expenditures. This is inclusive of an approximate $8.6 million shift in expenses for DHM and HMF from providers (hospitals) to health insurance subject to AB 3059, and cost offsets due to an estimated increase in prevented cases of NEC and BPD. CHBRP estimates AB 3059 would result in an additional 35 enrollees (1%) utilizing DHM and an additional 11 enrollees utilizing HMF.

In the first year postmandate, CHBRP estimates AB 3059 would lead to universal access to DHM in California through the removal of requirements for hospitals to be licensed as a tissue bank in order to provide DHM to patients, and that there would be a reduction in the average number of NEC and BPD cases of 0.62 and 1.75 cases per year, respectively, as well as a corresponding reduction in length of hospital stay (18 days for medically-treated NEC; 50 days for surgically-treated NEC; 26 days for BPD).

Context

The American Academy of Pediatrics (AAP) recommends exclusive feeding with human milk for the first 6 months of life, with the continuation of feeding for 1 year or longer as mutually desired by mother[1] and infant.[2] In addition, the AAP recommends that when mother's own milk is not available that donor human milk (DHM) be provided to all preterm and low-birthweight (LBW; <2,500 grams [5 pounds, 8 ounces]) infants. DHM is used primarily in neonatal intensive care unit (NICU) settings to prevent the development of necrotizing enterocolitis (NEC), bronchopulmonary dysplasia (BPD),

[1] The term "mother" is used here to refer to the person who is lactating and providing human milk to the infant.

[2] See full report for references.

and other poor health outcomes. It is provided through human milk banks that collect DHM, screen it for disease, pasteurize it, and freeze it for distribution to hospitals for use in the NICU setting.

NEC is a severe disease of the intestinal tract and is one of the main causes of morbidity and mortality among very low–birthweight (VLBW; <1,500 grams [3 pounds, 4 ounces]) infants. In 2017, the incidence of NEC among infants born with VLBW in California was 2.6%. Between 2% and 5% of all NICU admissions are infants with NEC. Approximately 15% of infants with NEC require surgery, and mortality rates are around 20%. In the most severe cases of NEC — which involve bowel perforation, peritonitis,[3] and sepsis — mortality rates approach 100%. Infants that do survive may face long-term complications from NEC such as intestinal issues, developmental delays and neurological impairment, and increased risk of other conditions such as blindness, hearing loss, and cerebral palsy.

Among preterm infants, the most prevalent, serious morbidity is BPD. BPD is a form of chronic lung impairment occurring as a result of lungs that do not develop fully in a newborn. It is estimated that 25% of VLBW infants develop BPD. The incidence of BPD increases with decreasing birthweight and gestational age. Four in five infants born at 22 to 24 weeks are diagnosed with BPD as compared to one in five born at 28 weeks. Roughly 95% of infants diagnosed with BPD are VLBW. Mortality rates among VLBW infants with BPD are estimated to be as high as 45%. Long-term consequences of BPD include increased risk of cardiovascular disease, impaired lung function, increased risk of respiratory infections, neurological impairments such as cerebral palsy, and vision and hearing problems. Infants with BPD may also need ongoing respiratory monitoring and support throughout their lifetime.

Bill Summary

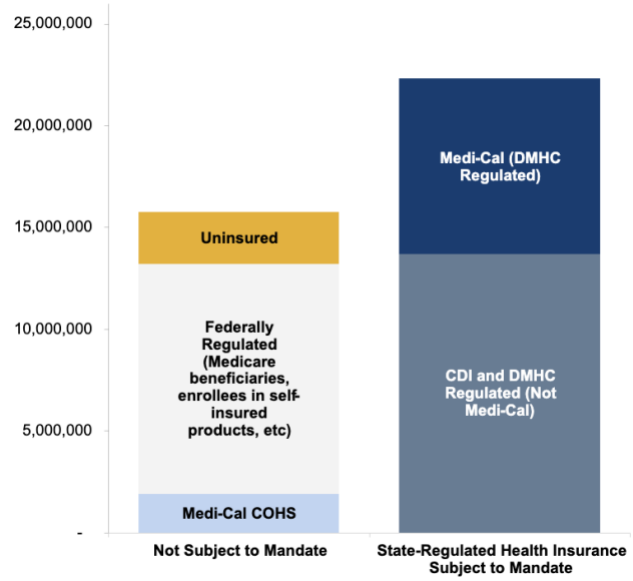
AB 3059 would require DMHC-regulated health plans and CDI-regulated policies to provide the same coverage for human milk and human milk derivatives as that afforded by the Medi-Cal program as of 1998.

The bill would also exempt general acute care hospitals from the requirement to hold a tissue bank license when storing or distributing human milk acquired from a mothers' milk bank, defined in statute as a nonprofit entity that procures, processes, stores, distributes, or uses human milk contributed by volunteer donors, in compliance with standards prescribed by the Human Milk Banking Association of North America (HMBANA).

Since 1998, California law has required the state's Medi-Cal program to provide coverage for human milk and human milk derivatives supplied by a mothers' milk bank for human consumption. Although the law does not define "human milk," "human milk derivatives," or details on coverage requirements, the Department of Health Care Services (DHCS), which administers the state's Medi-Cal program, published a policy letter highlighting the importance of breastfeeding for mothers and infants. The policy letter further specified that the timely provision of human milk must be covered if "a mother is unable to breastfeed due to medical reasons, and the infant cannot tolerate or has medical contraindications to the use of any formula, including elemental formulas."

Figure A notes how many Californians have health insurance that would be subject to AB 3059.

Figure A. Health Insurance in CA and AB 3059



Source: California Health Benefits Review Program, 2024.
Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

[3] Peritonitis is inflammation of the lining of the belly or abdomen.

Impacts

Benefit Coverage, Utilization, and Cost

Benefit coverage

CHBRP estimates that 39.13%, or 8,724,735 enrollees have coverage for DHM and HMF at baseline. This primarily includes Medi-Cal beneficiaries in DMHC-regulated plans.

Postmandate, CHBRP estimates that 100%, or 22,297,000 enrollees, will have coverage for DHM and HMF, a 155.56% increase. This increase is based on the CHBRP assumption that all noncompliant plans and policies at baseline would become compliant postmandate.

Utilization

Inpatient utilization of DHM and HMF

At baseline, CHBRP estimated that 3,471 enrollees, or 99% of VLBW and very preterm infants in California NICUs, utilize DHM in the inpatient setting. Postmandate, CHBRP estimated that 3,507, or 100%, of medically eligible enrollees would utilize DHM in the inpatient setting, an increase of 1% or 35 infants.

At baseline, CHBRP estimated that 1,041, or 30%, of medically eligible enrollees utilize HMF in the inpatient setting.[4] Postmandate, CHBRP estimated that 1,052, or 30%, of medically eligible enrollees would utilize HMF in the inpatient setting, an increase of 1% or 11 infants.

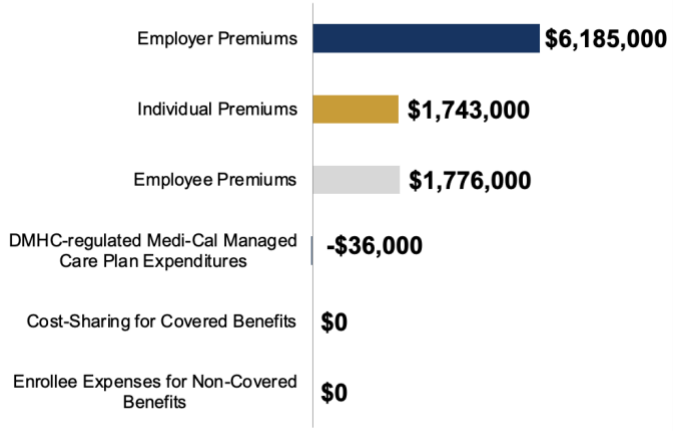
Outpatient utilization of DHM and HMF

At baseline, CHBRP estimates limited use of DHM and HMF in the outpatient setting due to medical necessity guidelines and utilization management approaches such as prior authorization. While coverage for DHM and HMF would increase to 100% postmandate, it is important to note that benefit coverage does not equal utilization. CHBRP assumed continued limited use of DHM in the outpatient setting postmandate due to the continued use of medical necessity guidelines and utilization management approaches and to access barriers such as availability of the local supply, access to a local milk bank, and the requirement of a prescription from a physician.

Expenditures

AB 3059 would increase total net annual expenditures by $9,668,000 for enrollees with DMHC-regulated plans and CDI-regulated policies (Figure B). This is inclusive of an approximate $8.6 million shift in expenses for DHM and HMF from providers (hospitals) to health insurance subject to AB 3059, and cost offsets due to an estimated increase in prevented cases of NEC and BPD.

Figure B. Expenditure Impacts of AB 3059



Source: California Health Benefits Review Program, 2024.
Key: DMHC = Department of Managed Health Care.

Medi-Cal

Although the insurance of Medi-Cal beneficiaries in DMHC-regulated plans is subject to AB 3059, if enacted, the bill would not impact their coverage. At baseline, Medi-Cal beneficiaries in DMHC-regulated plans have 100% coverage for human milk and human milk derivatives. In DMHC-regulated Medi-Cal plans, total premiums would decrease by $36,000 (0.0001%).

CalPERS

For enrollees associated with the California Public Employees' Retirement System (CalPERS) in DMHC-regulated plans, premiums would increase by 0.0079% ($0.0621 per member per month, or $553,000 total increase in expenditures).

[4] CHBRP assumes the remaining DHM-eligible enrollees receive DHM with milk fortifiers derived from nonhuman sources.

Covered California – individually purchased

Premiums for enrollees in individual plans purchased through Covered California would increase by a total of $1,307,000 in annual expenditures, a 0.0083% increase.

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 AB 3059.

Medical Effectiveness

CHBRP examined and summarized the available evidence regarding the effectiveness of DHM versus preterm formula for the prevention of NEC, BPD, LOS as well as growth and weight gain, and the effectiveness of HMF. CHBRP concluded there was:

- *Clear and convincing evidence* that DHM was more effective than preterm formula in the prevention of NEC and the prevention of BPD in preterm infants.
- *Limited evidence* that DHM is not as effective as preterm formula for weight gain, and a *preponderance of evidence* that DHM is no more effective than preterm formula for the prevention of LOS in preterm infants.
- *Inconclusive evidence* regarding the effectiveness of fortifiers derived from human milk versus bovine milk on outcomes for preterm infants. Note that this does not indicate that HMF and BMF are not effective in the prevention of negative health outcomes for preterm infants, but rather that neither is comparatively *more or less* effective than the other.

Public Health

In the first year postmandate, CHBRP estimates that there would be a reduction in the average number of NEC and BPD cases of 0.62 and 1.75 cases per year, respectively, as well as a corresponding reduction in length of hospital stay (18 days for medically-treated NEC; 50 days for surgically-treated NEC; 26 days for BPD). This estimate is supported by *clear and convincing evidence* that DHM is medically effective in preventing NEC and BPD in preterm infants and an estimated increase in utilization (1%) of DHM.

CHBRP estimates AB 3059 would lead to universal access to DHM in California through the removal of requirements for hospitals to be licensed as a tissue bank in order to provide DHM to their patients and through reimbursement of these treatments. This could reduce disparities in receipt of DHM between infants with an inpatient stay at a smaller hospital.

Long-Term Impacts

In the case of AB 3059, CHBRP assumes a 1% change in utilization of DHM, which would lead to a reduction in the average number of cases of NEC and BPD over time. As both NEC and BPD are conditions that leave survivors with long-term significant morbidities including cerebral palsy, growth and development challenges, and academic difficulties, the prevention of these conditions could have significant long-term consequences both for the infants and their family and caregivers.

Essential Health Benefits and the Affordable Care Act

AB 3059 would not require coverage for a new state benefit mandate that exceeds the definition of essential health benefits in California.