A REPORT TO THE 2023–2024 CALIFORNIA STATE LEGISLATURE

Analysis of California Assembly Bill 3059 Human Milk

APRIL 16, 2024

CHBRP

California Health Benefits Review Program (CHBRP)
Office of Research, University of California, Berkeley

www.chbrp.org

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

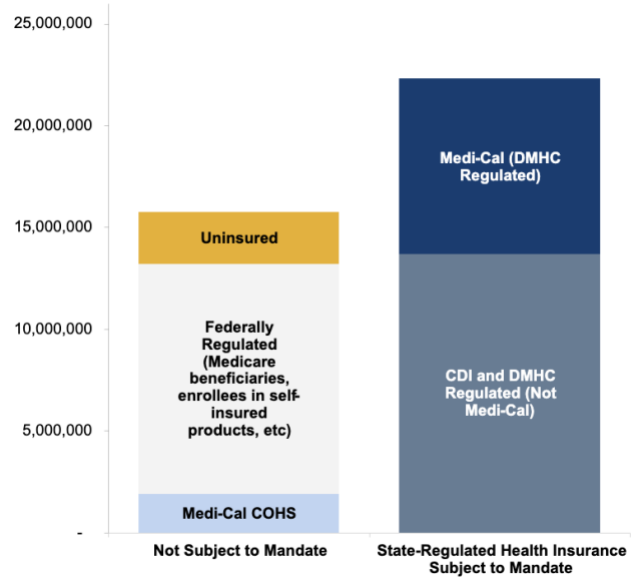
AB 3059 would require DMHC-regulated health plans and CDI-regulated policies to provide the same coverage for human milk and human milk derivatives as that afforded by the Medi-Cal program as of 1998.

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.

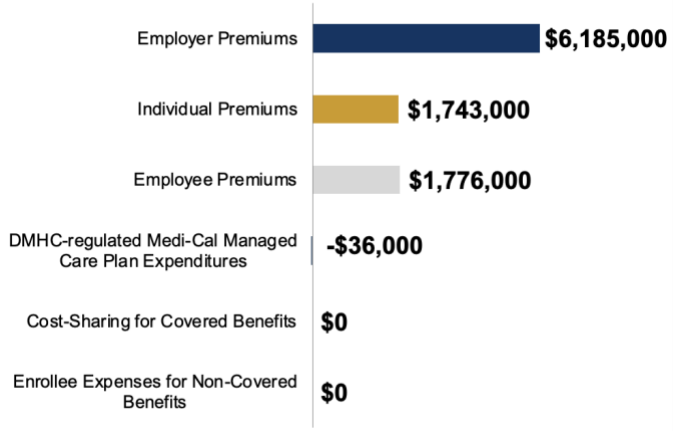
Outpatient utilization of DHM and HMF

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.

About CHBRP

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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Lists of Tables and Figures

Policy Context

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[5] conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 3059, Human Milk, as amended on March 11, 2024.

Bill-Specific Analysis of AB 3059, Human Milk

Bill Language

AB 3059 would require health plans regulated by DMHC and policies regulated by CDI to provide the same coverage for human milk and human milk derivatives as that afforded by the Medi-Cal program as of 1998. The full text of AB 3059 can be found in Appendix A.

California Regulating Agencies

DMHC: California Department of Managed Health Care

CDI: California Department of Insurance

DHCS: Department of Health Care Services which administers Medi-Cal

Relevant Populations

If enacted, AB 3059 would apply to the health insurance of approximately 22.3 million enrollees (58.6% of all Californians). This represents those who have commercial health insurance or health insurance through the California Public Employees' Retirement System (CalPERS) regulated by DMHC and CDI and Medi-Cal beneficiaries enrolled in DMHC-regulated plans. However, as discussed in the California Policy Landscape section below, human milk and human milk derivatives for human consumption are a covered benefit of the Medi-Cal program. Therefore, AB 3059 would not impact the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Analytic Approach and Key Assumptions

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. The 1998 law defines a mothers' milk bank 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).[6] Although the law does not define "human milk," "human milk derivatives," or details on coverage requirements, the DHCS, which administers the state's Medi-Cal program, published a policy letter highlighting the importance of breastfeeding for mothers and infants.[7] 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."[8]

CHBRP uses the following terms and definitions for this analysis:

- **Human milk:** milk lactated or expressed from the mammary gland of a human.
- **Donor human milk (DHM):** human milk supplied by a donor human milk bank. When referenced in this analysis, DHM does not include human milk derivatives (i.e., human milk fortifiers); fortifiers are explicitly mentioned when relevant to a discussion.

[5] CHBRP's authorizing statute is available at www.chbrp.org/about/faqs.
[6] Welfare and Institutions Code (WIC) Section 14132.34.
[7] CHBRP recognizes a parent may instead chestfeed or identify as someone other than the infant's mother; the language used in this description mirrors that which was used in the DHCS policy letter.
[8] DHCS Policy Letter 98-10 from December 10, 1998.

- **Donor human milk bank:** a person, firm, or corporation that engages in the not-for-profit procurement, processing, storage, distribution, or use of human milk, contributed by volunteer donors, in compliance with standards prescribed by the HMBANA. This definition is consistent with that of "mothers' milk bank" in California law. See California Policy Landscape for more information.
- **Human milk derivatives:** components of human milk, such as bioactive molecules that protect against infection and inflammation and contribute to organ development. Human milk derivatives include human milk fortifiers derived from humans, and exclude fortifiers derived from nonhuman sources.
- **Human milk fortifiers:** a nutritional supplement added to human milk to provide additional calories, protein, and vitamins to help promote infant growth and bone development. Human milk fortifiers may be derived from different sources, such as humans (i.e., human milk-derived fortifiers [HMF]) and cows (i.e., bovine milk-derived fortifiers [BMF]).
- **Mother's own milk:** human milk expressed or lactated directly from the birthing parent of the infant in receipt of said milk.

CHBRP also assumes that, if enacted, AB 3059 would not impact the terms and conditions of coverage for DHM, including cost sharing and utilization management.

Interaction With Existing State and Federal Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

DHM supplied by a mothers' milk bank that meets certain criteria is a covered benefit for eligible Medi-Cal beneficiaries.[9] California law defines a mothers' milk bank as any person, firm, or corporation that engages in the not-for-profit procurement, processing, storage, distribution, or use of human milk, contributed by volunteer donors, in compliance with standards prescribed by HMBANA.[10] The complete version of HMBANA's standards are proprietary and provided only to HMBANA-accredited member milk banks. The standards cover topics such as donor eligibility criteria, and protocols for milk collection, storage, and distribution (HMBANA, 2024).

It should be noted that terms and conditions of Medi-Cal coverage for DHM, such as place of service, eligibility criteria, and utilization management are not defined under existing law. DHCS has, however, published guidance on eligibility criteria for mothers and infants to receive pasteurized DHM as a covered Medi-Cal benefit (DHCS, 2023). DHCS has also published guidance on billing codes appropriate for DHM for Medi-Cal reimbursement (DHCS, 2023).

All California hospitals that collect, process, store, or distribute human milk collected from a mother exclusively for her own child must follow HMBANA standards.[11] The California Department of Public Health (CDPH) requires all hospitals that store DHM to hold a tissue bank license (CDPH, 2023). California law defines a tissue bank as a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings.[12] Transplantation is defined as the act or process of transferring tissue, including by ingestion, from a donor to the body of the donor or another human being.[13] Tissue is defined as a human, human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, oocytes, embryos, blood, other fluids, and any other portion of a human body; the definition does not include organs recovered for transplantation or

[9] Welfare and Institutions Code (WIC) 14132.34.
[10] WIC 14132.34(b).
[11] Health and Safety Code (HSC) 1648.
[12] HSC 1635(f).
[13] HSC 1635(g).

research purposes.[14] California requires tissue banks operating in California on or after July 1, 1992, to have a current and valid tissue bank license from CDPH.[15] The law includes exemptions for certain procedures; however, the storage or distribution of pasteurized human milk is not among them. California milk banks that meet the state's statutory definition of a mothers' milk bank that applied for a tissue bank license before January 1, 1995, are exempt from the application and annual renewal fee for a tissue bank license.[16] As discussed in the *Background* section, there are two milk banks that meet the state's definition of a mothers' milk bank: Mothers' Milk Bank in San Jose was founded in 1974, and the University of California Health Milk Bank was founded in 2020. Based on the aforementioned law, the University of California Health Milk Bank is required to hold a valid tissue bank license to operate, whereas the Mothers' Milk Bank in San Jose is exempt.

Human milk from donors who test reactive[17] for agents of viral hepatitis, human T-lymphotropic virus 1, human immunodeficiency virus (HIV), or syphilis is prohibited from being deposited to a milk bank.[18]

Previous legislation

The California Legislature previously proposed Senate Bill (SB) 1316 (2016), which contained some provisions related to AB 3059. SB 1316 would have, in part, required CDPH to adopt rules and regulations — based substantially on HMBANA guidelines — governing a licensed tissue bank that collects, processes, stores, or distributes human milk.[19] SB 1316 was held in the Senate Appropriations Committee.

Similar requirements in other states

Coverage for DHM

Seven states currently require commercial health insurance to provide coverage for DHM: Illinois, Kentucky, Louisiana, Maine, New Jersey, New York, and Washington (NCSL, 2022; Rose et al., 2022). In addition to California, 16 states and the District of Columbia provide coverage for DHM under their Medicaid program, including Connecticut, Florida, Illinois, Indiana, Kansas, Louisiana, Maine, Missouri, New Jersey, New York, Ohio, Oregon, Pennsylvania, Texas, Utah, and Washington (NCSL, 2022; Rose et al., 2022). Coverage requirements under both insurance types vary in each state based on length of time, medical conditions covered, utilization management requirements, coverage for fortifiers, and setting (i.e., coverage as outpatient vs. inpatient benefit) (NCSL, 2022; Rose et al., 2022). See Table 10 of Appendix B for more details on coverage requirements in different states.

Seven states have proposed legislation related to coverage for DHM. Legislation in Massachusetts[20] and Vermont[21] would require commercial coverage for DHM. Legislation in Nebraska[22] and Oklahoma[23] would require Medicaid coverage for DHM and DHM-derived products, respectively, under certain conditions. Virginia has proposed legislation requiring coverage for DHM under both Medicaid and commercial insurance under specified conditions.[24] New York[25] and Pennsylvania[26] have introduced legislation that would amend their existing laws regarding DHM coverage.

Regulation and DHM

Similar to California, New York and Maryland regulate human milk as a tissue and require tissue bank licenses for DHM banks (NCSL, 2022). Texas and Arkansas require DHM banks to follow guidelines set by their state health departments (ADH, 2021; NCSL, 2022). Pennsylvania requires all milk banks to be licensed and mandates milk banks be either

[14] HSC 1635(e).
[15] HSC 1635.1.
[16] HSC 1639.5.
[17] A reactive test result indicates the presence of antibodies or antigens of a condition, and that further investigation may be necessary; it is not the same as a positive result.
[18] HSC 1644.5.
[19] California Legislative Information. SB 1316 (2016). Available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB1316.
[20] Massachusetts House Bill 1030 (2024) and SB 696 (2023).
[21] Vermont House Bill 115 (2023).
[22] Nebraska Legislature Bill 13 (2024).
[23] Oklahoma SB 245 (2023).
[24] Virginia SB 499 (2024).
[25] New York Assembly Bill 7790, SB 3307, and SB 6674 (2024).
[26] Pennsylvania SB 500 and SB 673 (2023).

certified as a member in good standing of a professional association for the operation of milk banks or be otherwise compliant with Pennsylvania milk bank laws.[27]

New York[28] and Virginia[29] have proposed legislation requiring DHM banks to comply with specified standards and obtain a state license, respectively.

Federal Policy Landscape

Federal law and regulations

The term "human milk" is undefined in federal law. Federal regulations mention human milk as part of the definition of infant formula,[30] and in relation to the potential of excretion of drugs into human milk.[31]

The U.S. Food & Drug Administration (FDA) states on its website that it has not been involved in establishing state standards or voluntary guidelines for milk banks. The FDA recommends that people who are considering feeding their infants with donated human milk first consult with a healthcare provider and consider the possible safety risks. If they decide to move forward, the FDA recommends using milk from a source that has screened its milk donors and taken other precautions to ensure the safety of its milk; it recommends against feeding infants milk acquired directly from individuals or through the Internet (FDA, 2018).

Federal legislation

In 2023, the U.S. Congress introduced two bills related to DHM.[32] The bills would define DHM, authorize funding for DHM, and require the U.S. Department of Health & Human Services to promulgate regulations on DHM and develop a public awareness campaign with respect to the benefits and safety of DHM from FDA-registered DHM banks. As of the date this report was published, both bills were still actively moving through the federal legislative process.

Federal insurance coverage

TRICARE, the worldwide health care program for uniformed service members and their eligible family members, currently provides coverage for DHM for eligible enrollees under specified terms and conditions. To be eligible, an infant must have one or more of certain conditions — very low birthweight (<1500 grams [3 pounds, 4 ounces]), gastrointestinal anomaly, formula intolerance with documented feeding difficulty or weight loss, infant hypoglycemia, congenital heart disease, pre- or post-organ transplant, or other serious health conditions for which DHM is medically necessary and supports the treatment and recovery of the infant — and the mother's milk must be contraindicated, unavailable (due to a medical or psychological condition), or available but lacking in quantity or quality to meet the infant's needs. DHM is only covered for milk acquired through HMBANA-accredited human milk banks (TRICARE, 2022).

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 3059 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[33,34]

[27] Pennsylvania Law §443.14.
[28] New York SB 1788 (2024).
[29] Virginia SB 499 (2024).
[30] 21 Code of Federal Regulations (CFR) 106.3.
[31] 21 CFR 201.80, 201.57, 310.501; 16 CFR 1500.14.
[32] U.S. House Bill 5486 and SB 2819 (2023).
[33] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other-publications/issue-briefs.
[34] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

Essential Health Benefits

In California, nongrandfathered[35] individual and small-group health insurance is generally required to cover essential health benefits (EHBs).[36] In 2025, approximately 11.5% of all Californians will be enrolled in a plan or policy that must cover EHBs.[37]

States may require state-regulated health insurance to offer benefits that exceed EHBs.[38,39,40] Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace.

AB 3059 would not appear to exceed the definition of EHBs in California. As California considers whether to review the state's benchmark plan this year, it may be of interest to the state Legislature that the state of Washington is currently pursuing a new EHB benchmark plan that would include DHM for inpatient use for infants and parents that meet certain criteria (Wakely, 2023). Washington state statute requires any update to the state EHB benchmark plan to include coverage for DHM.[41]

[35] A grandfathered health plan is "a group health plan that was created — or an individual health insurance policy that was purchased — on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers." Available at: www.healthcare.gov/glossary/grandfathered-health-plan/.

[36] For more detail, see CHBRP's issue brief *Essential Health Benefits: An Overview of Benefits, Benchmark Plan Options, and EHBs in California*, available at www.chbrp.org/other-publications/issue-briefshttps://chbrp.org/other_publications/index.php.

[37] See CHBRP's resource *Sources of Health Insurance in California,* available at hwww.chbrp.org/other-publications/resources.

[38] ACA Section 1311(d)(3).

[39] 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.

[40] However, as laid out in the Final Rule on EHBs U.S. Department of Health and Human Services (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.

[41] Revised Code of Washington 48.43.715 and 48.43.815.

Background on Donor Human Milk Use in NICU Settings

AB 3059 would require coverage for human milk and human milk derivatives. Donor human milk (DHM) is used primarily in neonatal intensive care unit (NICU) settings to prevent the development of necrotizing enterocolitis (NEC), bronchopulmonary dysplasia (BPD), and other poor health outcomes. This background section provides information related to births of high-risk infants, the use of DHM in the NICU setting and rates of NEC and BPD to provide context for the consideration of the *Medical Effectiveness*, the *Benefit Coverage, Utilization, and Cost Impacts*, and the *Public Health Impacts* sections.

Donor Human Milk

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[42] and infant (AAP, 2012). In addition, the AAP recommends that when mother's own milk is not available that donor human milk (DHM) be provided to infants at increased risk for negative health outcomes. Four categories of high-risk infant births and the AAP recommendation for the use of DHM are presented below.

Table 1. Categories of Infants at Increased Risk and AAP Recommendations for Use of DHM

Risk Category	Definition	AAP Recommendation Related to DHM
Very Low Birthweight	<1,500 grams (3 pounds, 4 ounces)	Prioritized for use of DHM
Low Birthweight	<2,500 grams (5 pounds, 8 ounces)	Consider use of DHM depending on circumstances
Very Preterm	<32 weeks gestation	Consider use of DHM depending on circumstances
Preterm	<37 weeks gestation	Consider use of DHM depending on circumstances

Source:. Abrams et al., 2017; Meek and Noble, 2022.
Key: AAP = American Academy of Pediatrics; DHM = donor human milk.

DHM 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. The Human Milk Banking Association of North America (HMBANA) has accredited 30 nonprofit donor milk banks in the United States (HMBANA, n.d.). Two of these milk banks (Mother's Milk Bank and University of California Health Milk Bank) operate in California (HMBANA, n.d.). There is also one for-profit commercial milk bank operating in California (Prolacta).

Use of DHM in Inpatient Settings

The AAP recommends the use of DHM in the NICU setting as a medical therapy for infants that are born preterm with a priority for use in VLBW infants (AAP, 2012; Abrams et al., 2017; Meek and Noble, 2022). In addition, human milk can be used for infants with congenital gastrointestinal issues, critical heart defects, and severe growth restrictions (Abrams et al., 2017; Rose et al., 2022). Under some circumstances, mother's own milk is not available due to illness, medication use, or lack of production. Infants that have been born preterm or VLBW will often have mothers that may not have started

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

producing milk at the time of birth. In these situations, hospitals may rely on DHM to provide human milk to infants in the NICU. It is estimated that across the United States, 87% of hospitals with Level III or Level IV NICUs[43] have DHM available (Boundy, 2022). In cases where DHM is not available, infants may be transferred to a nearby hospital that does have DHM.

Use of DHM in Outpatient Settings

While the large majority of DHM is distributed for internal use in the NICU, the AAP recognizes that DHM may also be used in an outpatient setting for infants with complex medical conditions as deemed appropriate by their treating clinician for conditions such as severe congenital heart disease, intestinal failure, or gastroschisis (Abrams et al., 2017; Rose et al., 2022). The use of DHM in outpatient settings varies by the availability of local supply of DHM and requires a prescription from the physician and access to a local milk bank. In addition, DHM is more expensive than formula. Due to these barriers, DHM is not commonly used in outpatient settings.

Human Milk Fortifiers

As a complement to human milk, the AAP also recommends that VLBW infants receive human milk that has been appropriately fortified with proteins, minerals, and vitamins to ensure optimal nutrient intake and growth (Parker et al., 2021). Human milk fortifiers are typically derived from either human milk or cow's milk. DHM from HMBANA facilities is fortified in the NICU and is mostly done with BMF (Perrin, 2018). In 2015, it was estimated that 92% to 96% of Level III and Level IV NICU facilities used human milk fortifiers across the United States; of these, between 72% and 76% reported using BMF and 30% to 34% reported using HMF (Perrin, 2018).

Prevalence of Conditions Treated with DHM

The AAP recommends that infants born VLBW are given priority for treatment with DHM. These infants are at increased risk for death, medical complications, and tend to have worse health and later-life outcomes. In addition, they disproportionately account for admissions to the NICU and newborn health care costs compared to their peers born at normal birth weights (Chyn et al., 2021; Eichenwald and Stark, 2008). As shown in Table 2, in California in 2022, 9.1% of infants were born preterm, with 1.4% being classified as very preterm (<32 weeks) (NCHS, 2022). Similarly, 7.4% of infants born in California in 2022 were born LBW with 1.1% being born VLBW (NCHS, 2022). Infants born preterm may also be born LBW. In California in 2022, 68% of LBW deliveries were preterm; for VLBW deliveries, 99% were preterm (CDPH, 2024a). Similarly, in California in 2022, 56% of preterm (<37 weeks) and 95% of early preterm (<34 weeks) deliveries were born LBW (CDPH, 2024b). In comparison, less than 1% of term deliveries (39-41 weeks) were LBW (CDPH, 2024b).

This analysis focuses on the prevention of two severe diseases that impact preterm and VLBW infants: NEC and BPD. The prevalence and related consequences of these conditions are discussed below.

NEC is a severe disease of the intestinal tract and is one of the main causes of morbidity and mortality among VLBW infants. In 2017, the incidence of NEC among infants born VLBW in California was 2.6% (Goldstein et al., 2020). About 85% of all NEC cases are among VLBW or very preterm infants. Approximately 15% of infants with NEC require surgery, and mortality rates are around 20% (Frost et al., 2017). In the most severe cases of NEC — which involve bowel perforation, peritonitis,[44] and sepsis — mortality rates approach 100% (Ginglen and Butki, 2023). 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 (Bazacliu and Neu, 2019; Henry and Moss, 2009).

[43] NICUs are categorized into four levels (I, II, III, IV). Level III and IV provide care for the most complex and critically ill infants.
[44] Peritonitis is inflammation of the lining of the belly or abdomen.

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 (Jensen and Schmidt, 2014; Lee et al., 2022). 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 (Thebaud et al., 2019). Roughly 95% of infants diagnosed with BPD are VLBW (Thebaud et al., 2019). Mortality rates among VLBW infants with BPD are estimated to be as high as 45% (Lapcharoensap et al., 2015). 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 (Thebaud et al., 2019). Infants with BPD may also need ongoing respiratory monitoring and support throughout their lifetime (Thebaud et al., 2019).

Table 2. Prevalence of Conditions Treated with DHM Overall and by Race/Ethnicity, 2020-2022

Race/Ethnicity (a)	LBW (<2,500 g) (b)	VLBW (<1,500 g)	Preterm (<37 weeks) (c)	Very Preterm (<32 weeks)
Overall	7.4%	1.1%	9.1%	1.4%
Hispanic	6.9%	1.1%	9.2%	1.5%
Non-Hispanic				
American Indian/Alaska Native	7.8%	1.3%	11.7%	2.0%
Asian/Pacific Islander	8.4%	1.1%	9.0%	1.3%
Black	12.1%	2.3%	12.4%	2.6%
White	6.1%	0.9%	8.0%	1.2%

Source: California Health Benefits Review Program, 2024; NCHS, 2022.
Notes: (a) Overall data is for 2022, data by race/ethnicity is from 2020-2022.
(b) LBW is inclusive of VLBW.
(c) Preterm is inclusive of very preterm.
Key: DHM = donor human milk; g = grams; LBW = low birthweight; VLBW = very low birthweight.

Disparities[45]

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature. CHBRP found literature identifying disparities by race and ethnicity in the rates of the availability of human milk and birth outcomes. These disparities are described below.

Studies show that Black and Hispanic mothers are less likely to provide their own milk in the NICU as compared to White mothers. One study showed that Black, Hispanic, and White mothers initiated providing their milk similarly, but that infants born to Black and Hispanic mothers stopped receiving mother's own milk earlier than White mothers during NICU hospitalization (Parker et al., 2021). There are multiple factors that contribute to race/ethnic disparities in the provision of mother's own milk to VLBW infants in the NICU. Some barriers may include mothers' need to return to work, lack of access to breastfeeding or lactation support, maternal comorbidities, and transportation to the NICU (Goldstein et al., 2020). Given these barriers to providing mother's own milk, DHM can play an important role in fulfilling the need for human milk among infants in the NICU, yet there are also disparities in receipt of DHM in the hospital. For example, infants born to Black mothers are less likely to receive DHM compared to infants born to White mothers (Parker et al.,

[45] 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).

2021). As described below, there are many barriers to accessing DHM in the NICU that are associated with additional disparities.

As shown in Table 2, rates of preterm and VLBW vary significantly by race/ethnicity, with infants born to Black persons having rates of preterm and VLBW at much higher rate compared to infants born to persons of other race/ethnicities. While overall levels of VLBW births have been declining in recent years in California, racial/ethnic disparities persist. Compared to White infants, which have the lowest incidence of VLBW births in California, Black, American Indian/Alaska Native, Hispanic, and Asian/Pacific Islander infants all have relatively higher incidences of VLBW births (NCHS, 2022).

There are also disparities in the incidence of complications of VLBW and preterm births such as NEC and BPD. Among VLBW infants, there are racial/ethnic disparities in the incidence of NEC with Hispanic (1.33), Asian (1.32), and Black (1.29) infants have higher odds of NEC as compared to White infants born VLBW (1.0) (Goldstein et al., 2020). In addition, infants born to Black mothers had more severe cases of BPD with higher mortality rates and longer hospital stays compared to infants born to White mothers (Lewis et al., 2022).

Barriers to Accessing DHM in the NICU

There are multiple barriers to accessing DHM in the NICU. The primary barrier is that not all hospitals offer DHM (Boundy, 2022). The Centers for Disease Control and Prevention (CDC) has documented previously that 13% of U.S. hospitals with Level III or Level IV NICUs do not have DHM available (Boundy, 2022). Hospital provision of DHM varies by hospital size with a significant difference in the rate of providing DHM between the smallest and largest hospitals (58.5% vs. 95.7%, respectively) (Boundy, 2022). In addition, rates of provision vary by geographic region, with the Midwest hospitals having the highest rates (95.9%) and the Northeast hospitals having the highest rates (76.2%%) (Boundy, 2022). In three states, including California, there is an additional barrier for hospitals to provide DHM: state law requires that hospitals have a tissue bank license to store DHM on site.[46] This annual licensure requirement makes it difficult for smaller hospitals, who may lack infrastructure and administrative resources, to apply for and receive licensure each year. Additional factors that impact the availability of DHM at hospitals include adequate supply from milk banks, cost of DHM, and insurance reimbursement (Bai and Kuscin, 2021; Boundy, 2022).

Even among those U.S. hospitals that do offer DHM in the NICU setting, not all infants receive DHM. For example, as shown in Table 3, across the United States, 8.9% of Level IV NICUs report that only 1% to 19% of their VLBW infants receive DHM (Boundy, 2022). Approximately half of Level III and Level IV NICUs report that 80% of more of the VLBW infants receive DHM. (Boundy, 2022). Although the AAP recommends that all infants born VLBW receive DHM, of those U.S. hospitals that do offer DHM, rates of provision of DHM to VLBW infants vary widely: factors influencing provision of DHM at hospitals that store DHM include staff member training and awareness of the use of DHM as well as parental knowledge and attitudes toward the safety and benefits of using DHM (Bai and Kuscin, 2021; Boundy, 2022).

Table 3. Percentage of VLBW Infants Receiving DHM in Level III and Level IV NICU Settings, United States, 2020

Percent of Infants Receiving DHM in Level III and IV NICU	% of Level III NICUs	% of Level IV NICUs	Total (Level III and IV)
0% (i.e., DHM Not Available)	14.8%	2.2%	13.0%
>0-19%	4.4%	8.9%	5.0%
20-49%	9.9	11.1%	10.1%
50-79%	17.1%	17.8%	17.2%
≥80%	53.8%	60.0%	54.7%

[46] California Health & Safety Code §§1647-1648 (2010)

Source: California Health Benefits Review Program, 2024; Boundy, 2022.
Key: DHM = donor human milk; NICU = neonatal intensive care unit; VLBW = very low birthweight (<1,500 grams [3 pounds, 4 ounces]).
Note: NICUs are categorized into four levels (I, II, III, IV). Level III and IV provide care for the most complex and critically ill infants.

Societal Impact of NEC and BPD in California

The average length of a hospital stay for VLBW infants is 58 days (Buckle and Taylor, 2017; Klinger et al., 2006). Stays for infants that develop NEC or BPD are longer (Buckle and Taylor, 2017; Klinger et al., 2006). Families with infants who are hospitalized as a result of being born preterm or VLBW incur indirect costs, i.e., costs that are not covered by insurance (King et al., 2021; Zupancic, 2018). These indirect costs could include parent's loss of earnings (e.g., from changes in job status, missing work), costs associated with travel to visit the infant (e.g., gas, bus fare, parking, meals), and childcare costs for siblings (King et al., 2021). Evidence suggests that economic burdens can persist after hospitalizations as well (Carlton et al., 2023).

Specific to the long-term impacts of NEC, one study found approximately three-fourth of infants with NEC end up with long-term complications (Canvasser et al., 2023). These included long-term medical complications impacting not only aspects of the gastrointestinal system, but also the respiratory system, gross and fine motor stills, and neurocognitive outcomes (Canvasser et al., 2023). Nearly half needed an additional surgery after NICU discharge, and 39% reported that having NEC had impacted their quality of life in the long term (Canvasser et al., 2023). About one-quarter reported that having NEC created long-term impacts on their social relationships and that they had anxiety or worry about their body image (Canvasser et al., 2023). Parents surveyed reported that their health or mental health was impacted by their child's long-term complications (74%), that they experienced financial stress as a result of paying for medical care (43%), and that they had difficulty balancing work-life obligations due to the time needed to seek care for their child (50%) (Canvasser et al., 2023).

Studies of the impact of BPD have also found long-term societal impacts on parents, caregivers, and the BPD patient themselves (Lee et al., 2022). Caregivers of BPD patients report decreased sleep, increased depressive symptoms, and overall higher levels of stress (Lee et al., 2022). Although the impacts of BPD persisted after hospital discharge, the negative impacts on caregivers' quality of life subsided as time went on (Lee et al., 2022). In addition, long-term health consequences of BPD can involve additional hospitalizations and doctor's visits, which may impact caregivers' ability to work.

Medical Effectiveness

As discussed in the *Policy Context* section, AB 3059 would require DMHC-regulated plans and CDI-regulated policies to provide the same level of coverage for human milk and human milk derivatives as that afforded by the Medi-Cal program as of 1988. Additional information on donor human milk (DHM) use is included in the *Background on Donor Human Milk Use in NICU Settings* section. The medical effectiveness review summarizes the evidence[47] from 2014 to present on the effectiveness of DHM for the prevention of neonatal necrotizing enterocolitis (NEC) and bronchopulmonary dysplasia (BPD) for preterm infants with low or very low–birthweight. Where applicable, the evidence for other health outcomes such as growth and weight gain and late-onset sepsis (LOS) is presented.

Research Approach and Methods

The search was limited to studies published from 2014 to present. A total of 13 studies were included in the medical effectiveness review for this report, eight of which were systematic reviews or meta-analyses. 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.[48] 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.

Key Questions

1. Is DHM more effective than preterm formula at the prevention of NEC for preterm infants?
2. Is DHM more effective than preterm formula for the prevention of BPD in preterm infants?
3. Is DHM more effective than formula for growth and weight gain for preterm infants?
4. Is DHM more effective than formula for the prevention of LOS for preterm infants?
5. Are human milk–derived fortifiers (HMF) more effective than those derived from bovine milk (BMF) for health outcomes for preterm infants?

Outcomes Assessed

The main outcomes for this analysis are comparative rates of NEC and BPD for preterm infants who were given DHM versus formula. Also included are other common and relevant health outcomes for preterm (<37 weeks) and low-birthweight (LBW) infants (<2,500 g [5 pounds, 8 ounces]) such as growth and weight gain, and LOS.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the outcomes outlined above. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the

[47] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence in the *Medical Effectiveness Analysis and Research Approach* document (posted at www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis), 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.

[48] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis.

strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in Appendix C.

Effectiveness of DHM for the Prevention of NEC in Preterm Infants

NEC is a serious gut disorder affecting premature and LBW infants. Human milk contains essential immunoprotective factors like secretory IgA, lysozyme, and lactoferrin, which are crucial for the infant's health. Evidence suggests that feeding with maternal human milk can reduce the risk of NEC compared to preterm formula[49] feeding. One systematic review and meta-analysis (synthesizing the results of multiple studies) was conducted by Zhang and colleagues (Zhang et al., 2020). The meta-analysis was a combined analysis of 12 randomized controlled trials (RCTs) with a total of 2,677 infants that examined the impact of different doses of human milk on the prevention of NEC. The combined results demonstrated that premature infants fed mainly human milk had a significantly reduced rate of NEC as compared to those fed with formula (relative risk [RR] = 0.49, 95% confidence interval [CI]: 0.34–0.71, P <.05). They additionally reported that there was linear decline of the incidence of NEC proportional to increases of human milk in the overall milk intake.

In another meta-analysis conducted by Li and colleagues (Li et al., 2022), the authors assessed the combined impact of 11 RCTs with a total of 1,390 infants examining DHM versus formula for the prevention of NEC. They concluded that feeding preterm infants with DHM contributed to a reduction in the incidence of NEC (RR = 0.67, 95% CI: 0.48–0.93).

These findings are consistent with other meta-analytic results. In a 2019 systematic review and meta-analysis, Yu and colleagues (2019) assessed the combined impact of seven RCTs with a total of 876 infants. They reported that very low–birthweight (VLBW) infants who were fed DHM had a significantly lower risk of NEC compared to infants who were fed formula (odds ratio [OR] = 0.33, 95% CI: 0.18–0.59).

Another systematic review (Quigley et al., 2019) examined reported outcomes from 12 RCTs with a total of 1,979 infants comparing formula to DHM in the feeding of preterm or LBW infants and concluded that preterm or LBW infants who were fed formula either as a sole source or as supplement to human milk had a higher risk of developing NEC (OR = 1.87, 95% CI: 1.23– 2.85).

A 2018 systematic review (Miller et al., 2018) that included 42 studies with a total of over 20,000 infants covering a wide range of outcomes similarly reported a significant reduction in the incidence of NEC for infants who were fed DHM versus preterm formula, especially with higher doses (RR = 0.59, 95% CI: 0.39–0.89).

The evidence of the impact of DHM versus formula with regard to NEC requiring surgery is not as pronounced. One meta-analysis of four studies including 1,464 infants examined the impact of DHM for the prevention of NEC requiring surgery concluded that DHM did not demonstrate a significantly superior protective effect against surgical NEC as compared to preterm formula (RR = 0.45; 95% CI: 0.19–1.09) (Silano et al., 2019).

Summary of findings regarding the effectiveness of DHM versus preterm formula for the prevention of NEC: Based on evidence from five systematic reviews/meta-analyses and one policy brief, CHBRP concludes there is *clear and convincing evidence* that DHM is effective, versus preterm formula, in the prevention of NEC.

Figure 1. Impact of DHM versus Formula on the Prevention of NEC

[49] Preterm formula is a specialized infant formula designed to meet the unique nutritional needs of premature or low birth weight infants. It has a higher caloric density and increased levels of protein, vitamins, and minerals compared to standard infant formula to support catch-up growth and development in preterm babies.

Effectiveness of DHM for the Prevention of BPD in Preterm Infants

BPD is one of the most common complications after preterm birth. Human milk — both mother's own milk and DHM — has been shown to offer protection against BPD compared to formula. Research indicates that human milk, particularly mother's own milk, plays a significant role in reducing the frequency of BPD in VLBW preterm infants. Multiple systematic reviews and meta-analyses have been conducted examining this issue.

In one systematic review and meta-analysis conducted by Lu and colleagues (Lu et al., 2023), it was found that both mother's own milk and DHM have a significant protective effect in reducing the frequency of BPD occurrence compared to formula (OR = 0.62; 95% CI: 0.41–0.94, p = 0.02). Furthermore, they concluded that even when the available amount of human milk is insufficient, a diet of at least 50% volume of human milk still provided a significant protective effect against BPD (OR = 0.72; 95% CI: 0.55–0.93, p = 0.01).

One systematic review and meta-analysis (Villamor-Martinez et al., 2018) included three RCTs and eight observational studies on the effects of DHM on BPD and other respiratory outcomes. Their analysis of the results of the RCTs yielded nonsignificant results regarding the impact of DHM versus preterm formula for the prevention of BPD (RR = 0.89; 95% CI: 0.60–1.32); however, the combined analysis of the eight observational studies showed a strong effect of DHM supplementation for the prevention of BPD (RR = 0.78; 95% CI: 0.67–0.90) and the authors overall conclusion was that the evidence suggested significant protective effect of DHM versus preterm formula for BPD.

Summary of findings regarding the effectiveness of DHM versus preterm formula for the prevention of BPD in preterm and LBW infants: Based on evidence from two systematic reviews/meta-analytic reports, CHBRP concludes that there is *clear and convincing evidence* that DHM is effective, versus preterm formula, in the prevention of BPD in premature and low-birthweight infants.

Figure 2. Impact of DHM versus Preterm Formula for the Prevention of BPD in Preterm and Low-Birthweight Infants

Effectiveness of DHM for Weight Gain and Growth in Preterm Infants

Unlike the evidence for the prevention of NEC, the literature does not suggest a clear advantage of unfortified DHM over preterm formula for weight gain and linear growth of premature and VLBW infants. One umbrella review (North et al., 2021) combined other relevant systematic reviews of existing studies on milk type and weight gain for low and VLBW infants. The authors included 26 systematic reviews that in total covered 150 studies examining the impact of different types of milk feeding. They concluded that both preterm formula and protein-fortified human milk were associated with increased weight gain and linear growth compared to unfortified human milk.

Another systematic review (Quigley et al., 2019) examined reported outcomes from 12 studies covering 1,879 preterm or LBW infants, comparing preterm formula to unfortified DHM in the feeding of preterm or LBW infants. The results of their meta-analysis indicated that infants who were fed preterm formula experienced more rapid weight gain, and linear growth than infants who were fed unfortified DHM.

This agrees with the results of another systematic review published in 2022 that included a total of 1,390 infants over 11 RCTs (Li et al., 2022). The results of the combined meta-analysis revealed that preterm formula had significant advantages in weight gain, head circumference, and body length growth of premature infants compared to unfortified DHM.

Summary of findings regarding the effectiveness of unfortified DHM versus preterm formula for weight gain and growth in premature and LBW infants: Based on evidence from three systematic reviews/meta-analytic reports and one policy brief, CHBRP concludes there is *limited evidence* unfortified DHM does not appear to be as effective as preterm formula for weight gain and growth.

Figure 3. Impact of DHM versus Preterm Formula on Weight Gain and Growth in Premature and Low-Birthweight Infants

Effectiveness of DHM for the Prevention of LOS in Preterm Infants

There is evidence that human milk may provide protection against infection in newborn infants compared to formula. However, the research consensus is that this protective property is largely limited to mother's own milk, which contains bioactive substances such as lactoferrin that reduce the risk of sepsis and NEC in infants (Knoop et al., 2020). Therefore, for the purposes of this bill analysis, which focuses on DHM, the following analysis will report on the evidence regarding DHM relative to preterm formula in the reduction of LOS in preterm infants.

A recent systematic review and meta-analysis has examined and summarized the research in this area. Li and colleagues (Li et al., 2022) examined 11 RCTs with a total of 1,390 infants, six of which included a comparison of DHM and preterm formula. A meta-analysis of the combined results of these trials revealed no significant difference between DHM and preterm formula in the incidence of sepsis (RR = 1.04; 95% CI: 0.86–1.26, p = 0.68). Reasons behind this difference between mother's own milk and DHM with regard to the prevention of LOS include the loss of certain nutrients during storage, and the pasteurization process, which can result in the loss of certain antibodies and cellular components of breast milk.

Summary of findings regarding the effectiveness of DHM versus preterm formula for the prevention of LOS for premature and low-birthweight infants: Based on evidence from one systematic review and meta-analysis covering 11 RCTs, CHBRP concludes that there is a *preponderance of evidence* that DHM is **no more effective** than preterm formula in the prevention of sepsis in preterm and LBW infants.

Effectiveness of Fortifiers Derived from Human Milk versus Bovine Milk on Outcomes for Preterm Infants

Fortifiers are supplements that are added to expressed human milk to provide additional nutrients for preterm infants. There are two main types of fortifiers, those made from bovine-based protein (BMF), and those made from human milk (HMF). Much like the outcomes described above, the relative effectiveness of human versus bovine-derived fortifiers is dependent on the outcome in question.

One systematic review (Ananthan, 2020) examined the evidence from six RCTs comparing HMFs and BMFs. A meta-analysis of the combined results revealed that fortification using HMF decreased the risk of NEC (RR = 0.38; 95% CI: 0.15–0.95) but resulted in slower weight gain (p < .05) as compared with BMF. However, the reviewers noted that some included studies had a risk of bias or were not adequately powered and therefore concluded that, given the low quality of evidence, additional well-designed RCTs with a lower risk of bias are required in order to validate these findings.

Another systematic review published in 2019 (Premkumar, 2019) similarly had the goal of comparing outcomes from preterm infants. Their systematic search resulted in only one RCT with sufficient quality for inclusion. They reported that HMFs relative to BMFs did not decrease the risk of NEC in preterm infants fed exclusively with breast milk, and there was no difference between the fortifiers for growth, feeding intolerance, or LOS.

Summary of findings regarding fortifiers derived from human milk versus bovine milk on outcomes for preterm infants: Based on evidence from two systematic reviews/meta-analyses, CHBRP concludes that the evidence is *inconclusive*. 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.

Figure 4. Effectiveness of HMF versus BMF on Outcomes for Preterm Infants

Summary of Findings

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 human milk–derived fortifiers. 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. 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 LOS in preterm infants. Additionally, evidence was *inconclusive* regarding the effectiveness of fortifiers derived from human milk versus bovine milk for the prevention of the above health outcomes.

Benefit Coverage, Utilization, and Cost Impacts

As discussed in the *Policy Context* section, AB 3059 would require health plans regulated by DMHC and policies regulated by CDI to provide the same level of coverage for human milk and human milk derivatives as that afforded by the Medi-Cal program as of 1988.

In addition to commercial enrollees, 74% of enrollees associated with CalPERS and 80% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[50] As noted in the *Policy Context* section, AB 3059 would impact the benefit coverage of CalPERS enrollees' but not that of Medi-Cal beneficiaries enrolled in DMHC-regulated plans, as the latter population has fully compliant coverage at baseline.

This section reports the potential incremental impacts of AB 3059 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

AB 3059 impacts the benefit coverage of two separate services: donor human milk (DHM) and human milk–derived fortifiers (HMF). As discussed in the *Medical Effectiveness* section, there is *clear and convincing evidence* that, in comparison to preterm formula, DHM is effective in the prevention of necrotizing enterocolitis (NEC), and *clear and convincing evidence* that it is effective in the prevention of bronchopulmonary dysplasia (BPD). Accordingly, CHBRP includes the potential impact of AB 3059, if enacted, with regards to NEC and BPD in its cost approach. The *Medical Effectiveness* section also found *inconclusive evidence* on the general use of HMF versus BMF in health outcomes for preterm and VLBW infants.

Very low–birthweight (VLBW; <1,500 grams [3 pounds, 4 ounces]) and very preterm (<32 weeks) infants at risk of NEC and BPD are treated in the inpatient setting of a neonatal intensive care unit (NICU). Once they are no longer at risk for these conditions, they may be discharged. For this reason, CHBRP assumed that postmandate utilization of DHM and HMF would be primarily in inpatient settings, with utilization in outpatient settings limited based on medical necessity guidelines and/or utilization management.

Assumptions for Baseline Coverage and Utilization

CHBRP assumed that 100% of VLBW and very preterm infants require DHM for some portion of their NICU stay. At baseline, 87% of California hospitals with Level III and Level IV NICUs[51] provide DHM for VLBW infants (Boundy, 2022). CHBRP assumed that all VLBW/very preterm infants in these hospitals receive DHM for prevention of NEC and BPD, and that all DHM was fortified with either an HMF or bovine-derived fortifier (BMF) (Perrin, 2018). CHBRP assumed that 70% of NICUs used BMF and 30% of NICUs used HMF (Perrin, 2018).

CHBRP assumed that in the remaining 13% of California hospitals that do not currently provide DHM, 1% of all VLBW/very preterm infants statewide receive care. In practice, most VLBW/very preterm infants hospitalized in NICUs that cannot provide DHM are transferred to those that can for numerous reasons, including access to higher levels of care, specialized equipment, and specialists. Smaller hospitals that do not provide DHM also have smaller NICUs.[52]

For baseline estimates related to cost and coverage, CHBRP assumed the following:

[50] For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at www.chbrp.org/other-publications/resources.
[51] NICUs are categorized into four levels (I, II, III, IV). Levels III and IV provide care for the most complex and critically ill infants.
[52] Communication with V. Flaherman, March 6, 2024; Communication with E. Miller, April 12, 2024.

- California hospitals providing DHM and HMF are not billing for these treatment services outside of inpatient payment bundles.[53]
- The average cost of providing DHM per VLBW infant, very preterm infant, or infant with a medical necessity where DHM is appropriate is $1,000 per NICU stay (Tetarbe et al., 2024). The average cost of providing HMF is $10,000 per NICU stay (Ganapathy et al., 2011).

Assumptions for Postmandate Coverage and Utilization

Postmandate, CHBRP assumed that all hospitals providing DHM would bill for DHM and HMF outside of the inpatient bundle, due to the new coverage requirements mandated in AB 3059. CHBRP assumed that reimbursement for DHM would increase utilization in hospitals not currently providing DHM by VLBW and very preterm infants. CHBRP also assumed that the proportion of medically eligible enrollees utilizing HMF would not change postmandate, given the inconclusive evidence of its effectiveness in comparison to BMF.

CHBRP assumed that cost sharing for DHM and HMF would not change postmandate, and that DMHC-regulated plans and CDI-regulated policies may require prior authorization and/or step therapy for HMF, which would impact utilization.

Finally, CHBRP also assumed that the removal of the tissue bank license requirement for hospitals would lead all hospitals to provide DHM for all VLBW and very preterm infants; this would lead to an increase in DHM utilization by VLBW and very preterm infant enrollees who were Medi-Cal beneficiaries in DMHC-regulated plans and commercial enrollees in DMHC-regulated plans and CDI-regulated policies.

Assumptions for Cost Offsets

CHBRP made the following assumptions about the prevention of NEC and BPD in VLBW infants:

NEC

- 2.6% of VLBW infants develop NEC; this risk is reduced by 68% when DHM is provided in the NICU (Yang et al., 2020).
- 85% of NEC cases can be treated without surgery, 15% can be treated surgically (Frost et al., 2017).
- DHM reduces the length of hospital stay due to NEC by 18 days for medical NEC and 50 days for surgical NEC (Buckle and Taylor, 2017). NEC increases the average cost of a NICU stay by $176,172.81.

BPD

- 25% of VLBW infants develop BPD (Jensen and Schmidt, 2014; Lee et al., 2022); this risk is reduced by 20% when VLBW infants are provided with DHM (Villamor-Martínez et al., 2018).
- BPD increases the cost of a NICU stay by $68,775.14 (Johnson et al., 2014).
- The adjusted NICU length of stay for VLBW infants with and without BPD was 84.1 days (95% CI: 82.8–85.6) and 58.1 days (Klinger et al., 2006).

For further details on the underlying data sources and methods used in this analysis, please see Appendix D.

[53] Inpatient bundles are type of payment structure in which different health care providers who are treating patients for the same or related conditions are paid an overall sum for taking care of a patient's condition rather than being paid for each individual treatment, test, or procedure. In doing so, providers are rewarded for coordinating care, preventing complications and errors, and reducing unnecessary or duplicative tests and treatments (CMS, n.d.).

Baseline and Postmandate Benefit Coverage

Below, Table 4 provides estimates of how many Californians have health insurance that would have to comply with AB 3059 in terms of 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.

Table 4. Impacts of AB 3059 on Benefit Coverage, 2025

	Baseline (2025)	Postmandate Year 1 (2025)	Increase/ Decrease	Percentage Change
Total enrollees with health insurance subject to state benefit mandates (a)	22,297,000	22,297,000	0	0.00%
Total enrollees with health insurance impacted by AB 3059	13,572,265	13,572,265	0	0.00%
Percentage of enrollees with coverage for mandated benefit	39.13%	100.00%	60.87%	155.56%
Number of enrollees with fully compliant coverage for mandated benefit	8,724,735	22,297,000	13,572,265	155.56%

Source: California Health Benefits Review Program, 2024.
Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[54]
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

Baseline and Postmandate Utilization and Unit Cost

[54] For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at www.chbrp.org/other-publications/resources.

Table 5 provides estimates of the impacts of AB 3059 on utilization and unit cost of DHM and HMF.

Table 5. Impacts of AB 3059 on Utilization and Unit Cost, 2025

	Baseline (2025)	Postmandate Year 1 (2025)	Increase/ Decrease	Percentage Change
Enrollees eligible for mandated benefit for medical necessity (infants at risk for NEC)	3,507	3,507	-	0.00%
Enrollees eligible for mandated benefit for medical necessity (infants at risk for BPD)	3,507	3,507	-	0.00%
Utilization				
Enrollees utilizing of mandated benefit				
DHM				
Inpatient	3,471	3,507	35	1.01%
Outpatient	n/a	n/a	-	0.00%
HMF				
Inpatient	1,041	1,052	11	1.01%
Outpatient	n/a	n/a	-	0.00%
Unit Costs				
Unit Cost of DHM (per NICU stay)	$1,000	$1,000	-	0.00%
Unit Cost of HMF (per NICU stay)	$10,000	$10,000		
Expenses paid for benefit by providers (hospitals) for services related to the mandated benefit that are not covered by insurance				
DHM per NICU stay	$1,000	$0	n/a	n/a
HMF per NICU stay	$10,000	$0	n/a	n/a
Expenditures for benefit per enrollee covered by insurance				
DHM	$0	$1,000	n/a	n/a
HMF	$0	$10,000	n/a	n/a
Cost offsets				
Utilization of NEC-related services	29.79	29.17	(0.62)	-2.08%
Utilization of BPD-related services	703.06	701.31	(1.75)	-0.25%
Average Cost of NEC-related hospitalization	$176,172.81	$176,172.81	-	0.00%
Average Cost of BPD-related hospitalization	$68,775.14	$68,775.14	-	0.00%
Total Cost Offsets for NEC-related services	n/a	n/a	-$109,219.21	n/a
Total Cost Offsets for BPD-Related Services	n/a	n/a	-$120,581.14	n/a

Source: California Health Benefits Review Program, 2024.
Key: BPD = bronchopulmonary dysplasia; DHM = donor human milk; HMF = human milk-derived fortifiers; NEC = necrotizing enterocolitis; NICU = neonatal intensive care unit.

Inpatient Utilization of DHM and HMF

CHBRP estimated the number of eligible enrollees by multiplying the number of infants born in California enrolled in DMHC-regulated plans and CDI-regulated policies each year by the estimated rate of VLBW (1.1%). At baseline, CHBRP estimated that 3,471 enrollees, or 99% of VLBW/very preterm infants in California NICUs, utilize DHM in the inpatient setting. Postmandate, CHBRP estimates that 3,507, or 100%, of enrollees at risk for BPD or NEC would utilize DHM in the inpatient setting, an increase of 1% or 35 infants.

At baseline, CHBRP estimated that 30%, or 1,041 enrollees, of medically eligible enrollees utilize HMF in the inpatient setting.[55] Postmandate, CHBRP estimates that 1,052, or 100%, 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.

Average Cost, Expenses, and Expenditures of DHM and HMF

At baseline, CHBRP assumed an average treatment cost of $1,000 for DHM during an inpatient stay and an average treatment cost of $10,000 for HMF (Ganapathy et al., 2011; Tetarbe et al., 2024). CHBRP assumed that DHM and HMF treatment expenses are currently paid for by the hospitals in which the infants are treated at baseline.

Postmandate, CHBRP assumed no changes in the average treatment cost of either DHM or HMF. CHBRP assumed that DHM and HMF expenses would be covered by DMHC-regulated plans and CDI-regulated policies for medically eligible enrollees, postmandate.

Baseline and Postmandate Expenditures

Below,

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

Table 6 provides estimates of the impacts of AB 3059 on expenditures, which include premiums, enrollee cost sharing, and enrollee expenses for noncovered benefits.

Table 6. Impacts of AB 3059 on Expenditures, 2025

	Baseline (2025)	Postmandate Year 1 (2025)	Increase/ Decrease	Percentage Change
Premiums				
Employer-sponsored (a)	$64,203,365,000	$64,208,997,000	$5,632,000	0.0088%
CalPERS employer (b)	$6,974,311,000	$6,974,864,000	$553,000	0.0079%
Medi-Cal (excludes COHS) (c)	$30,043,243,000	$30,043,207,000	-$36,000	-0.0001%
Enrollee Premiums (expenditures)				
Enrollees, individually purchased insurance	$20,751,015,000	$20,752,758,000	$1,743,000	0.0084%
Outside Covered California	$5,089,510,000	$5,089,946,000	$436,000	0.0086%
Through Covered California	$15,661,505,000	$15,662,812,000	$1,307,000	0.0083%
Enrollees, group insurance (d)	$20,397,418,000	$20,399,194,000	$1,776,000	0.0087%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	$15,689,351,000	$15,689,351,000	$0	0.0000%
Expenses for noncovered benefits (e) (f)	$0	$0	$0	0.0000%
Total Expenditures	$158,058,703,000	$158,068,371,000	$9,668,000	0.00006%

Source: California Health Benefits Review Program, 2024.
Notes: (a) In some cases, a union or other organization. Excludes CalPERS.
(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents.
(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition, it seems likely that there would also be a proportional decrease of $0.01 million for Medi-Cal beneficiaries enrolled in COHS managed care.
(d) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.
(e) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.
(f) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).
Key: CalPERS = California Public Employees' Retirement System; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

Postmandate, AB 3059 would result in changes in total premiums paid by employers and enrollees of DMHC-regulated plans and CDI-regulated policies of newly covered benefits. Total employee-sponsored premiums would increase by $5,632,000 (0.0088% increase) and total CalPERS employer premiums would increase by $553,000 (a 0.0079% increase). Total Medi-Cal premiums would decrease by $36,000 (0.0001% decrease). Enrollee premiums (expenditures) would increase $1,743,000 for enrollees with individually purchased insurance, a 0.0084% increase, and $1,776,000 for enrollees with group insurance, a 0.0087% increase.

CHBRP estimates that enrollee expenses for covered benefits would not increase postmandate.

Postmandate, CHBRP estimates that hospitals expenses for provision of DHM and HMF to medically eligible infants would decrease by $8,585,000.

Below, Table 7 provides estimates of the impacts of AB 3059 on provider (hospital) expenditures for noncovered benefits.

Table 7. Impacts of AB 3059 on Provider (Hospital) Expenditures, 2025

	Baseline (2025)	Postmandate Year 1 (2025)	Increase/ Decrease	Percentage Change
Provider expenses				
Expenses for noncovered benefits (a) (b)				
DHM	$2,146,000	$0	-$2,146,000	-100.00%
HMF	$6,439,000	$0	-$6,439,000	-100.00%
Total Provider Expenditures	$8,585,000	$0	-$8,585,000	-100.0000%

Source: California Health Benefits Review Program, 2024.
Notes: (a) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.
(b) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).

Key: DHM = donor human milk; HMF = human milk–derived fortifiers.

Premiums

At the end of this section, 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).

Changes in premiums as a result of AB 3059 would vary by market segment. Note that such changes are related to the number of enrollees (see

Table 5, Table 8, and Table 9), with health insurance that would be subject to AB 3059.

Postmandate, for DMHC-regulated plans, the changes in total premiums would range from a decrease of $0.0004 PMPM in Medi-Cal Under 65 plans (0.0001% decrease) to an increase of $0.0637 PMPM (0.0097% increase) in DMHC-regulated small-group commercial plans.

Postmandate, for CDI-regulated plans, the changes in total premiums would range from a decrease of $0.0004 PMPM in large-group commercial plans (<0.0001% decrease) to an increase of $0.0637 PMPM in individual commercial plans (0.0087% increase).

Enrollee Expenses

AB 3059–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see

Table 5, Table 8, and Table 9) with health insurance that would be subject to AB 3059 expected to use the relevant tests, treatments, or services during the year after enactment.

Postmandate, for DMHC-regulated plans, the changes in total enrollee expenses would range from a decrease of $0.0004 PMPM (0.0001% decrease) in Medi-Cal Under 65 plans to an increase of $0.0098 PMPM (0.0012% increase) in small-group commercial plans. For CDI-regulated plans, changes in total enrollee expenditures would range from a decrease of $0.0004 PMPM (<0.0001 % decrease) in small group commercial plans to $0.0098 (0.0010% increase) PMPM in individual commercial plans.

It is possible that some enrollees incurred expenses related to DHM or HMF in the inpatient or outpatient settings for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Average enrollee out-of-pocket expenses per user

CHBRP assumed that DMHC-regulated plans and/or CDI-regulated policies will not impose cost sharing for DHM or HMF in the inpatient setting.

It is possible that enrollees could incur out-of-pocket expenses for DHM in the outpatient setting, but CHBRP is unable to estimate these expenses based on available data. The presence of a deductible not yet met for the year[56] could result in the enrollee paying the full unit cost, however hitting the annual out-of-pocket maximum[57] would result in the enrollee having no further cost sharing.

Postmandate Administrative Expenses and Other Expenses

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

Potential Offsets

Prevention of NEC

CHBRP assumed that the average cost of a NEC-related hospitalization was $176,172.81 (see

[56] For estimates of enrollees in plans and policies with deductibles, see CHBRP's resource *Deductibles in State-Regulated Health Insurance*, available at www.chbrp.org/other-publications/resources.
[57] For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to $250, or $500 for enrollees in the "bronze plans" available from Covered California, the state's ACA marketplace (H&SC 1342.73; IC 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.

Table 5). At baseline, CHBRP assumed an average utilization of NEC-related services of 29.79 enrollees. Postmandate, CHBRP estimates a reduction in NEC-related services of 2.08%, to 29.17 enrollees. CHBRP estimates total offsets of $109,219.21 for NEC-related hospitalizations.

Prevention of BPD

CHBRP assumed that the average cost of a BPD-related hospitalization was $68,775.14. At baseline, CHBRP assumed an average utilization of BPD-related services by 703.06 enrollees. Postmandate, CHBRP estimates a reduction in NEC-related services of 0.25%, to 701.31 enrollees. CHBRP estimates total offsets of $120,581.14 for BPD-related hospitalizations.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 5, Table 8, and Table 9), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 3059.

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 3059.

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

At baseline, CHBRP assumed that noncovered benefits are paid for by 87% of hospitals. Postmandate, CHBRP assumes that 100% of hospitals would begin billing for medically necessary DHM and HMF outside of the inpatient payment bundle.

Table 8. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2025

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS (b)*	*Medi-Cal (excludes COHS) (c)*		*Large Group*	*Small Group*	*Individual*	**Total**
					Under 65	*65+*				
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	7,864,000	2,161,000	2,378,000	894,000	7,791,000	818,000	293,000	62,000	36,000	22,297,000
Total enrollees in plans/policies subject to AB3059	7,864,000	2,161,000	2,378,000	894,000	7,791,000	818,000	293,000	62,000	36,000	22,297,000
Premium Costs										
Average portion of premium paid by employer (e)	$527.59	$461.25	$0.00	$650.10	$263.09	$554.83	$585.36	$533.03	$0.00	$101,220,919,000
Average portion of premium paid by enrollee	$138.26	$193.80	$716.04	$133.99	$0.00	$0.00	$215.50	$174.12	$736.61	$41,148,433,000
Total Premium	**$665.85**	**$655.05**	**$716.04**	**$784.09**	**$263.09**	**$554.83**	**$800.87**	**$707.15**	**$736.61**	**$142,369,352,000**
Enrollee Expenses										
Cost-sharing for covered benefits (deductibles, copays, etc.)	$48.82	$146.52	$209.79	$56.41	$0.00	$0.00	$119.25	$246.95	$203.25	$15,689,351,000
Expenses for noncovered benefits (f)	$0.05	$0.05	$0.05	$0.05	$0.00	$0.00	$0.00	$0.05	$0.05	$8,585,000
Total Expenditures	**$714.72**	**$801.62**	**$925.88**	**$840.56**	**$263.09**	**$554.83**	**$920.12**	**$954.15**	**$939.91**	**$158,067,288,000**

Source: California Health Benefits Review Program, 2024.
Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents.
(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.
(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[58]
(e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.
(f) 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 covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[58] For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at www.chbrp.org/other-publications/resources.

Table 9. Postmandate Change in Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2025

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS (b)*	Medi-Cal (excludes COHS) (c)		*Large Group*	*Small Group*	*Individual*	**Total**
					Under 65	*65+*				
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	7,864,000	2,161,000	2,378,000	894,000	7,791,000	818,000	293,000	62,000	36,000	22,297,000
Total enrollees in plans/policies subject to AB3059	7,864,000	2,161,000	2,378,000	894,000	7,791,000	818,000	293,000	62,000	36,000	22,297,000
Premium Costs (postmandate change)										
Average portion of premium paid by employer (e)	$0.0470	$0.0449	$0.0000	$0.0515	-$0.0004	$0.0000	-$0.0003	$0.0429	$0.0000	$6,149,000
Average portion of premium paid by enrollee	$0.0123	$0.0189	$0.0601	$0.0106	$0.0000	$0.0000	-$0.0001	$0.0140	$0.0637	$3,520,000
Total Premium	$0.0594	$0.0637	$0.0601	$0.0621	-$0.0004	$0.0000	-$0.0004	$0.0569	$0.0637	**$9,668,000**
Enrollee Expenses (postmandate change)										
Cost-sharing for covered benefits (deductibles, copays, etc.)	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Expenses for noncovered benefits (f)	-$0.0532	-$0.0539	-$0.0539	-$0.0531	$0.0000	$0.0000	$0.0000	-$0.0539	-$0.0539	-$8,585,000
Total Expenditures	$0.0062	$0.0098	$0.0063	$0.0090	-$0.0004	$0.0000	-$0.0004	$0.0031	$0.0098	**$1,083,000**
Postmandate Percent Change										
Percent change insured premiums	0.0089%	0.0097%	0.0084%	0.0079%	-0.0001%	0.0000%	0.0000%	0.0081%	0.0087%	0.0068%
Percent Change total expenditures	0.0009%	0.0012%	0.0007%	0.0011%	-0.0001%	0.0000%	0.0000%	0.0003%	0.0010%	0.0007%

Source: California Health Benefits Review Program, 2024.
Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).
(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents.
(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[59]
(e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.
(f) 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 covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[59] For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at www.chbrp.org/other-publications/resources.

Public Health Impacts

As discussed in the *Policy Context* section, AB 3059 would require health plans regulated by DMHC and policies regulated by CDI to provide the same level of coverage for human milk and human milk derivatives as that afforded by the Medi-Cal program as of 1988. The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[60] of AB 3059 on outcomes such as necrotizing enterocolitis (NEC) and bronchopulmonary dysplasia (BPD). See *Long-Term Impacts* for discussion of premature death and economic loss.

Estimated Public Health Outcomes

As presented in the *Medical Effectiveness* section, there is ***clear and convincing evidence*** that donor human milk (DHM) is **effective** in preventing NEC and BPD. In addition, there is ***limited evidence*** to suggest that DHM is **not as effective** as preterm formula for weight gain in preterm infants. There is a ***preponderance of evidence*** that DHM **is no more effective** than preterm formula in the prevention of sepsis in preterm infants. Finally, there is ***inconclusive evidence*** regarding the effectiveness of fortifiers derived from human milk versus bovine milk on the prevention of negative health outcomes in preterm infants. This section will only consider public health outcomes for conditions that have *clear and convincing* evidence: (NEC and BPD).

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, it is estimated that as a result of AB 3059, 35 additional very low–birthweight (VLBW) infants would receive DHM during their NICU stay. This is estimated to result in a reduction in cases of NEC by an average of 0.62 cases per year and a reduction in cases of BPD by an average of 1.75 cases per year. In addition, by reducing the number of NEC and BPD cases there would be a reduction in the length of hospital stay (18 days for medically-treated NEC; 50 days for surgically-treated NEC; 26 days for BPD) per case prevented.

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 assumed increase in utilization (1%) of DHM.

Impact on Disparities[61]

As described in the *Background* section, disparities in the provision of DHM exist by hospital size and resource level. Within the first 12 months 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 their patients and through reimbursement of these treatments. This could reduce disparities in receipt of DHM among infants with an inpatient stay at a smaller hospital.

Impact on Racial or Ethnic Disparities

As described in the *Background* section, disparities in rates of VLBW and NEC exist with infants born to Black mothers[62] having poorer birth outcomes compared to infants born to white mothers. While it is possible that the increase in the

[60] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.
[61] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.
[62] The term "mother" is used here to refer to the person who birthed the infant.

provision of DHM in smaller, lower-resourced hospitals could address some of this disparity, it is unknown to what extent this would occur.

The impact of AB 3059 on reducing documented disparities among racial and ethnic groups (see the *Background* section) is unknown because data are unavailable to estimate changes in the utilization of DHM among newly covered enrollees.

Long-Term Impacts

In this section, CHBRP estimates the long-term impact of AB 3059, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and derived 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

Use of donor human milk (DHM) has been associated with long-term cost savings across several studies and an increase in quality-adjusted life years (QALYs) in one study. Hampson et al. found that an exclusive human milk diet resulted in cost savings of $16,309 per infant by reducing adverse clinical events, and that this amount increased to $117,239 when considering societal costs (Hampson et al., 2019). In a study conducted in Canada, Trang et al. found that postdischarge costs were lower in the group fed with DHM ($46,440) compared with the formula-fed group ($55,102), with an incremental cost-effectiveness ratio of $5,328 per case of averted necrotizing enterocolitis (NEC) (Trang et al., 2018). In a study done in the United Kingdom, Mahon et al. estimated that QALY gain per infant was 0.088 if an infant received only DHM in the neonatal intensive care unit (NICU), and that the value per QALY was $2,897 per infant (converted to 2024 $USD) (Mahon et al., 2016). Postdischarge, Mahon et al. estimated 0.12 gained QALYs per infant over a lifetime (Mahon et al., 2016).

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable 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 disparities, premature death, and economic loss.

In the case of AB 3059, CHBRP estimates a 1% change in utilization of DHM which would lead to a reduction in the average number of cases of NEC and bronchopulmonary dysplasia (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 (Lapcharoensap et al., 2015), the prevention of these conditions could have significant long-term consequences both for the infants and their family and caregivers.

Impacts on Premature Death and Economic Loss

Premature death

Premature death, measured by years of potential life lost (YPLL), is often defined as death occurring before the age of 75 years (NCI, 2019).[63] Therefore, the death of an infant would result in a large impact on YPLL. It is estimated that among very low–birthweight (VLBW) infants mortality occurs in 10% to 50% of infants with NEC and 45% of infants with BPD (Ginglen and Butki, 2023; Lapcharoensap et al., 2015). The medical effectiveness literature review did not find any evidence that evaluated if DHM leads to a reduction in mortality rates, yet it is possible that through the reduction in cases of NEC (average of 0.62 cases/year) and BPD (average of 1.75 cases/year) that over time there could be a reduction in death among VLBW infants due to AB 3059. Infant death is particularly traumatic for parents, who then experience

[63] For more information about CHBRP's public health methodology, see www.chbrp.org/about/analysis-methodology/public-health-impact-analysis.

subsequent significant physical and psychological impacts such as anxiety and depression, newly diagnosed chronic health conditions, and posttraumatic stress disorder (Currie et al., 2019).

Economic loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill. As presented in the *Public Health* section, the provision of DHM to VLBW infants can reduce the incidence of NEC and BPD and lead to a reduction in the length of hospital stay (18 days for medically-treated NEC; 50 days for surgically-treated NEC; 26 days for BPD). This reduction could result in a saving of economic loss that occurs when parents have to take time off of work to be with their infant in the hospital. Furthermore, as both NEC and BPD are associated with long-term caregiving responsibilities, prevention of these conditions could also reduce time missed from work and improve productivity among caregivers. In addition, as AB 3059 is expected to have a reduction in mortality over time, there could also be savings associated with the reduction in YPLL.

Appendix A. Text of Bill Analyzed

On February 16, 2024, the California Assembly Committee on Health requested that CHBRP analyze AB 3059, as amended on March 11, 2024.

ASSEMBLY BILL **NO. 3059**

Introduced by Assembly Member Weber

February 16, 2024

An act to amend ~~Sections 1367.005 and 1635.1 of~~ *Section 1635.1 of, and to add Section 1367.624 to,* the Health and Safety Code, and to ~~amend Section 10112.27 of~~ *add Section 10123.864 to* the Insurance Code, relating to human milk.

LEGISLATIVE COUNSEL'S DIGEST

AB 3059, as amended, Weber. Human milk.

Existing law licenses and regulates tissue banks and generally makes a violation of the requirements applicable to tissue banks a crime. Existing law exempts a "mothers' milk bank," as defined, from paying a licensing fee to be a tissue bank.

This bill would specify that a general acute care hospital is not required to have a license to operate a tissue bank to store or distribute pasteurized human milk that was obtained from a mothers' milk bank.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, requires the Department of Managed Health Care to license and regulate health care service plans and makes a willful violation of the act a crime. Other existing law requires the Department of Insurance to regulate health insurers. Existing law requires ~~an individual or small group health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2017, to include, at a minimum, coverage for essential health benefits pursuant to the federal Patient Protection and Affordable Care Act. Under existing law, essential health benefits include, among other things, certain maternity and newborn care.~~ *health care service plans and health insurers, as specified, to provide certain health benefits and services, including, among others, maternity hospital stays, inpatient hospital and ambulatory maternity services, and maternal mental health programs.*

This bill would ~~specify that coverage of essential health benefits under a health care service plan or health insurance policy includes, with respect to maternity and newborn care,~~ *require a health care service plan contract or health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2025, to cover* the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988.

Because a violation of the bill's provisions by a health care service plan 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 Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. *Section 1367.624 is added to the Health and Safety Code, to read:*

1367.624. *A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2025, shall cover the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988.*

SEC. 2. *Section 1635.1 of the Health and Safety Code is amended to read:*

1635.1. (a) Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.

(b) This chapter does not apply to any of the following:

(1) The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.

(2) The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

(3) The collection of tissue by an individual physician and surgeon from their patient or the implantation of tissue by an individual physician and surgeon into their patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

(4) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

(5) The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 486.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the tissue, has been designated by the Secretary of Health and Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute care hospital.

(7) The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, are stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines, and are used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of their license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California-licensed tissue bank, been stored in strict accordance with the device's or product's package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner's own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:

(A) A list of all practitioners to whom the notice applies.

(B) Acknowledgment that each listed practitioner uses the medical device or biologic product in the scope and authority of their license and practice for the purposes of direct patient care as described in this paragraph.

(C) A statement that each listed practitioner agrees to strictly abide by the directions for storage in the device's or product's package insert and any other manufacturer instructions and guidelines.

(D) Acknowledgment by each practitioner that the medical device or biologic product shall not be resold or distributed.

(9) The collection, processing, storage, or distribution of any organ, as defined in paragraph (2) of subdivision (c) of Section 1635, within a single general acute care hospital, as defined in subdivision (a) of Section 1250, operating a Medicare-approved transplant program.

(10) The storage of allograft tissue by a person if all of the following apply:

(A) The person, as defined in Section 1635, is a hospital, or an outpatient setting regulated by the Medical Board of California pursuant to Chapter 1.3 (commencing with Section 1248), including an ambulatory surgical center.

(B) The person maintains a log that includes the date on which the allograft tissue was received, the expiration date of the allograft tissue, the date on which each allograft tissue is used for clinical purposes, and the disposition of any allograft tissue samples that remain unused at the time the allograft tissue expires.

(C) The allograft tissue meets all of the following:

(i) The allograft tissue was obtained from a tissue bank licensed by the state.

(ii) Each allograft tissue is individually boxed and labeled with a unique identification number and expiration date so that opening the shipping container will not disturb or otherwise alter any of the allograft tissue that is not being utilized.

(iii) The allograft tissue is intended for the express purpose of implantation into or application on a patient.

(iv) The allograft tissue is not intended for further distribution.

(v) The allograft tissue is registered with the FDA and designated to be maintained at ambient room temperature requiring no refrigeration.

(11) The storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

(12) The storage or distribution of pasteurized human milk that was obtained from a mothers' milk bank, as defined in Section 14132.34 of the Welfare and Institutions Code, by a general acute care hospital.

***SEC. 3**. Section 10123.864 is added to the Insurance Code, to read:*

***10123.864**. A health insurance policy, except a specialized health insurance policy, that is issued, amended, delivered, or renewed on or after January 1, 2025, shall cover the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988.*

***SEC. 4**. 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.

~~SECTION 1. Section 1367.005 of the Health and Safety Code is amended to read:~~

~~1367.005. (a)An individual or small group health care service plan contract issued, amended, or renewed on or after January 1, 2017, shall include, at a minimum, coverage for essential health benefits pursuant to the federal Patient Protection and Affordable Care Act (PPACA) and as outlined in this section. For purposes of this section, "essential health benefits" means all of the following:~~

~~(1)Health benefits within the categories identified in Section 1302(b) of PPACA: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care.~~

~~(2)(A)The health benefits covered by the Kaiser Foundation Health Plan Small Group HMO 30 plan (federal health product identification number 40513CA035) as this plan was offered during the first quarter of 2014, as follows, regardless of whether the benefits are specifically referenced in the evidence of coverage or plan contract for that plan:~~

~~(i)Medically necessary basic health care services, as defined in subdivision (b) of Section 1345 and Section 1300.67 of Title 28 of the California Code of Regulations.~~

~~(ii)The health benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in the following sections: Sections 1367.002, 1367.06, and 1367.35 (preventive services for children); Section 1367.25 (prescription drug coverage for contraceptives); Section 1367.45 (AIDS vaccine); Section 1367.46 (HIV testing); Section 1367.51 (diabetes); Section 1367.54 (alpha-fetoprotein testing); Section 1367.6 (breast cancer screening); Section 1367.61 (prosthetics for laryngectomy); Section 1367.62 (maternity hospital stay); Section 1367.63 (reconstructive surgery); Section 1367.635 (mastectomies); Section 1367.64 (prostate cancer); Section 1367.65 (mammography); Section 1367.66 (cervical cancer); Section 1367.665 (cancer screening tests); Section 1367.67 (osteoporosis); Section 1367.68 (surgical procedures for jaw bones); Section 1367.71 (anesthesia for dental); Section 1367.9 (conditions attributable to diethylstilbestrol); Section 1368.2 (hospice care); Section 1370.6 (cancer clinical trials); Section 1371.5 (emergency response ambulance or ambulance transport services); subdivision (b) of Section 1373 (sterilization operations or procedures); Section 1373.4 (inpatient hospital and ambulatory maternity); Section 1374.56 (phenylketonuria); Section 1374.17 (organ transplants for HIV); Section 1374.72 (mental health parity); and Section 1374.73 (autism/behavioral health treatment).~~

~~(iii)Any other benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in those statutes.~~

~~(iv)The health benefits covered by the plan that are not otherwise required to be covered under this chapter, to the extent required pursuant to Sections 1367.18, 1367.21, 1367.215, 1367.22, 1367.24, and 1367.25, and Section 1300.67.24 of Title 28 of the California Code of Regulations.~~

~~(v)Any other health benefits covered by the plan that are not otherwise required to be covered under this chapter.~~

~~(B)If there are any conflicts or omissions in the plan identified in subparagraph (A) as compared with the requirements for health benefits under this chapter that were enacted prior to December 31, 2011, the requirements of this chapter shall be controlling, except as otherwise specified in this section.~~

~~(C)Notwithstanding subparagraph (B) or any other provision of this section, the home health services benefits covered under the plan identified in subparagraph (A) shall be deemed to not be in conflict with this chapter.~~

~~(D)For purposes of this section, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343) shall apply to a contract subject to this section. Coverage of mental health and substance use disorder services pursuant to this paragraph, along with any scope and duration limits imposed on the benefits, shall be in compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law~~

~~110-343), and all rules, regulations, or guidance issued pursuant to Section 2726 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-26).~~

~~(3)With respect to habilitative services, in addition to any habilitative services and devices identified in paragraph (2), coverage shall also be provided as required by federal rules, regulations, and guidance issued pursuant to Section 1302(b) of PPACA. Habilitative services and devices shall be covered under the same terms and conditions applied to rehabilitative services and devices under the plan contract. Limits on habilitative and rehabilitative services and devices shall not be combined.~~

~~(4)With respect to pediatric vision care, the same health benefits for pediatric vision care covered under the Federal Employees Dental and Vision Insurance Program vision plan with the largest national enrollment as of the first quarter of 2014. The pediatric vision care benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any vision services covered under the plan identified in paragraph (2).~~

~~(5)With respect to pediatric oral care, the same health benefits for pediatric oral care covered under the dental benefit received by children under the Medi-Cal program as of 2014, including the provision of medically necessary orthodontic care provided pursuant to the federal Children's Health Insurance Program Reauthorization Act of 2009. The pediatric oral care benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any dental or orthodontic services covered under the plan identified in paragraph (2).~~

~~(6)With respect to maternity and newborn care, the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988. The benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any maternity or newborn services covered under the plan identified in paragraph (2).~~

~~(b)Treatment limitations imposed on health benefits described in this section shall be no greater than the treatment limitations imposed by the corresponding plans identified in subdivision (a), subject to the requirements set forth in paragraph (2) of subdivision (a).~~

~~(c)Except as provided in subdivision (d), this section does not permit a health care service plan to make substitutions for the benefits required to be covered under this section, regardless of whether those substitutions are actuarially equivalent.~~

~~(d)To the extent permitted under Section 1302 of PPACA and any rules, regulations, or guidance issued pursuant to that section, and to the extent that substitution would not create an obligation for the state to defray costs for any individual, a plan may substitute its prescription drug formulary for the formulary provided under the plan identified in subdivision (a) if the coverage for prescription drugs complies with the sections referenced in clauses (ii) and (iv) of subparagraph (A) of paragraph (2) of subdivision (a) that apply to prescription drugs.~~

~~(e)A health care service plan, or its agent, solicitor, or representative, shall not issue, deliver, renew, offer, market, represent, or sell any product, contract, or discount arrangement as compliant with the essential health benefits requirement in federal law, unless it meets all of the requirements of this section.~~

~~(f)This section applies regardless of whether the plan contract is offered inside or outside the California Health Benefit Exchange created by Section 100500 of the Government Code.~~

~~(g)This section does not exempt a plan or a plan contract from meeting other applicable requirements of law.~~

~~(h)This section does not prohibit a plan contract from covering additional benefits, including, but not limited to, spiritual care services that are tax deductible under Section 213 of the Internal Revenue Code.~~

~~(i)Subdivision (a) does not apply to any of the following:~~

~~(1)A specialized health care service plan contract.~~

~~(2)A Medicare supplement plan.~~

~~(3)A plan contract that qualifies as a grandfathered health plan under Section 1251 of PPACA or any rules, regulations, or guidance issued pursuant to that section.~~

~~(j)This section shall not be implemented in a manner that conflicts with a requirement of PPACA.~~

~~(k)An essential health benefit is required to be provided under this section only to the extent that federal law does not require the state to defray the costs of the benefit.~~

~~(l)This section does not obligate the state to incur costs for the coverage of benefits that are not essential health benefits as defined in this section.~~

~~(m)A plan is not required to cover, under this section, changes to health benefits that are the result of statutes enacted on or after December 31, 2011.~~

~~(n)(1)The department may adopt emergency regulations implementing this section. The department may, on a one-time basis, readopt any emergency regulation authorized by this section that is the same as, or substantially equivalent to, an emergency regulation previously adopted under this section.~~

~~(2)The initial adoption of emergency regulations implementing this section and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.~~

~~(3)The initial adoption of emergency regulations implementing this section made during the 2015–16 Regular Session of the Legislature and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.~~

~~(4)The director shall consult with the Insurance Commissioner to ensure consistency and uniformity in the development of regulations under this subdivision.~~

~~(5)This subdivision shall become inoperative on July 1, 2018.~~

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

~~(1)"Habilitative services" means health care services and devices that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology, and other services for people with disabilities in a variety of inpatient or outpatient settings, or both. Habilitative services shall be covered under the same terms and conditions applied to rehabilitative services under the plan contract.~~

~~(2)(A)"Health benefits," unless otherwise required to be defined pursuant to federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA, means health care items or services for the diagnosis, cure, mitigation, treatment, or prevention of illness, injury, disease, or a health condition, including a behavioral health condition.~~

~~(B)"Health benefits" does not mean any cost-sharing requirements such as copayments, coinsurance, or deductibles.~~

~~(3)"PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.~~

~~(4)"Small group health care service plan contract" means a group health care service plan contract issued to a small employer, as defined in Section 1357.500.~~

~~SEC. 2.Section 1635.1 of the Health and Safety Code is amended to read:~~

~~1635.1.(a)Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.~~

~~(b)This chapter does not apply to any of the following:~~

~~(1)The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.~~

~~(2)The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.~~

~~(3)The collection of tissue by an individual physician and surgeon from their patient or the implantation of tissue by an individual physician and surgeon into their patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.~~

~~(4)The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.~~

~~(5)The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 486.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the tissue, has been designated by the Secretary of Health and Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.~~

~~(6)The storage of prepackaged, freeze-dried bone by a general acute care hospital.~~

~~(7)The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, are stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines, and are used for the express purpose of implantation into a patient.~~

~~(8)The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of their license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California-licensed tissue bank, been stored in strict accordance with the device's or product's package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner's own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:~~

~~(A)A list of all practitioners to whom the notice applies.~~

~~(B)Acknowledgment that each listed practitioner uses the medical device or biologic product in the scope and authority of their license and practice for the purposes of direct patient care as described in this paragraph.~~

~~(C)A statement that each listed practitioner agrees to strictly abide by the directions for storage in the device's or product's package insert and any other manufacturer instructions and guidelines.~~

~~(D)Acknowledgment by each practitioner that the medical device or biologic product shall not be resold or distributed.~~

~~(9)The collection, processing, storage, or distribution of any organ, as defined in paragraph (2) of subdivision (c) of Section 1635, within a single general acute care hospital, as defined in subdivision (a) of Section 1250, operating a Medicare-approved transplant program.~~

~~(10)The storage of allograft tissue by a person if all of the following apply:~~

~~(A)The person, as defined in Section 1635, is a hospital, or an outpatient setting regulated by the Medical Board of California pursuant to Chapter 1.3 (commencing with Section 1248), including an ambulatory surgical center.~~

~~(B)The person maintains a log that includes the date on which the allograft tissue was received, the expiration date of the allograft tissue, the date on which each allograft tissue is used for clinical purposes, and the disposition of any allograft tissue samples that remain unused at the time the allograft tissue expires.~~

~~(C)The allograft tissue meets all of the following:~~

~~(i)The allograft tissue was obtained from a tissue bank licensed by the state.~~

~~(ii)Each allograft tissue is individually boxed and labeled with a unique identification number and expiration date so that opening the shipping container will not disturb or otherwise alter any of the allograft tissue that is not being utilized.~~

~~(iii)The allograft tissue is intended for the express purpose of implantation into or application on a patient.~~

~~(iv)The allograft tissue is not intended for further distribution.~~

~~(v)The allograft tissue is registered with the FDA and designated to be maintained at ambient room temperature requiring no refrigeration.~~

~~(11)The storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.~~

~~(12)The storage or distribution of pasteurized human milk that was obtained from a mothers' milk bank, as defined in Section 14132.34 of the Welfare and Institutions Code, by a general acute care hospital.~~

~~SEC. 3.Section 10112.27 of the Insurance Code is amended to read:~~

~~10112.27. (a)An individual or small group health insurance policy issued, amended, or renewed on or after January 1, 2017, shall include, at a minimum, coverage for essential health benefits pursuant to the federal Patient Protection and Affordable Care Act (PPACA) and as outlined in this section. This section shall exclusively govern the benefits a health insurer must cover as essential health benefits. For purposes of this section, "essential health benefits" means all of the following:~~

~~(1)Health benefits within the categories identified in Section 1302(b) of PPACA: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care.~~

~~(2)(A)The health benefits covered by the Kaiser Foundation Health Plan Small Group HMO 30 plan (federal health product identification number 40513CA035) as this plan was offered during the first quarter of 2014, as follows, regardless of whether the benefits are specifically referenced in the plan contract or evidence of coverage for that plan:~~

~~(i)Medically necessary basic health care services, as defined in subdivision (b) of Section 1345 of the Health and Safety Code and Section 1300.67 of Title 28 of the California Code of Regulations.~~

~~(ii)The health benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in the following sections of the Health and Safety Code: Sections 1367.002, 1367.06, and 1367.35 (preventive services for children); Section 1367.25 (prescription drug coverage for contraceptives); Section 1367.45 (AIDS vaccine); Section 1367.46 (HIV testing); Section 1367.51 (diabetes); Section 1367.54 (alpha-fetoprotein testing); Section 1367.6 (breast cancer screening); Section 1367.61 (prosthetics for laryngectomy); Section 1367.62 (maternity hospital stay); Section 1367.63 (reconstructive surgery); Section 1367.635 (mastectomies); Section 1367.64 (prostate cancer); Section~~

~~1367.65 (mammography); Section 1367.66 (cervical cancer); Section 1367.665 (cancer screening tests); Section 1367.67 (osteoporosis); Section 1367.68 (surgical procedures for jaw bones); Section 1367.71 (anesthesia for dental); Section 1367.9 (conditions attributable to diethylstilbestrol); Section 1368.2 (hospice care); Section 1370.6 (cancer clinical trials); Section 1371.5 (emergency response ambulance or ambulance transport services); subdivision (b) of Section 1373 (sterilization operations or procedures); Section 1373.4 (inpatient hospital and ambulatory maternity); Section 1374.56 (phenylketonuria); Section 1374.17 (organ transplants for HIV); Section 1374.72 (mental health parity); and Section 1374.73 (autism/behavioral health treatment).~~

~~(iii)Any other benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in those statutes.~~

~~(iv)The health benefits covered by the plan that are not otherwise required to be covered under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code, to the extent otherwise required pursuant to Sections 1367.18, 1367.21, 1367.215, 1367.22, 1367.24, and 1367.25 of the Health and Safety Code, and Section 1300.67.24 of Title 28 of the California Code of Regulations.~~

~~(v)Any other health benefits covered by the plan that are not otherwise required to be covered under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.~~

~~(B)If there are any conflicts or omissions in the plan identified in subparagraph (A) as compared with the requirements for health benefits under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code that were enacted before December 31, 2011, the requirements of Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code shall control, except as otherwise specified in this section.~~

~~(C)Notwithstanding subparagraph (B) or any other provision of this section, the home health services benefits covered under the plan identified in subparagraph (A) shall not be in conflict with Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.~~

~~(D)For purposes of this section, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343) shall apply to a policy subject to this section. Coverage of mental health and substance use disorder services pursuant to this paragraph, along with any scope and duration limits imposed on the benefits, shall be in compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343), and all rules, regulations, and guidance issued pursuant to Section 2726 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-26).~~

~~(3)With respect to habilitative services, in addition to any habilitative services and devices identified in paragraph (2), coverage shall also be provided as required by federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA. Habilitative services and devices shall be covered under the same terms and conditions applied to rehabilitative services and devices under the policy. Limits on habilitative and rehabilitative services and devices shall not be combined.~~

~~(4)With respect to pediatric vision care, the same health benefits for pediatric vision care covered under the Federal Employees Dental and Vision Insurance Program vision plan with the largest national enrollment as of the first quarter of 2014. The pediatric vision care services covered pursuant to this paragraph shall be in addition to, and shall not replace, any vision services covered under the plan identified in paragraph (2).~~

~~(5)With respect to pediatric oral care, the same health benefits for pediatric oral care covered under the dental benefit received by children under the Medi-Cal program as of 2014, including the provision of medically necessary orthodontic care provided pursuant to the federal Children's Health Insurance Program Reauthorization Act of 2009. The pediatric oral care benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any dental or orthodontic services covered under the plan identified in paragraph (2).~~

~~(6)With respect to maternity and newborn care, the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988. The benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any maternity or newborn services covered under the plan identified in paragraph (2).~~

~~(b)Treatment limitations imposed on health benefits described in this section shall be no greater than the treatment limitations imposed by the corresponding plans identified in subdivision (a), subject to the requirements set forth in paragraph (2) of subdivision (a).~~

~~(c)Except as provided in subdivision (d), this section does not permit a health insurer to make substitutions for the benefits required to be covered under this section, regardless of whether those substitutions are actuarially equivalent.~~

~~(d)To the extent permitted under Section 1302 of PPACA and any rules, regulations, or guidance issued pursuant to that section, and to the extent that substitution would not create an obligation for the state to defray costs for any individual, an insurer may substitute its prescription drug formulary for the formulary provided under the plan identified in subdivision (a) if the coverage for prescription drugs complies with the sections referenced in clauses (ii) and (iv) of subparagraph (A) of paragraph (2) of subdivision (a) that apply to prescription drugs.~~

~~(e)A health insurer, or its agent, producer, or representative, shall not issue, deliver, renew, offer, market, represent, or sell any product, policy, or discount arrangement as compliant with the essential health benefits requirement in federal law, unless it meets all of the requirements of this section. This subdivision shall be enforced in the same manner as Section 790.03, including through the means specified in Sections 790.035 and 790.05.~~

~~(f)This section applies regardless of whether the policy is offered inside or outside the California Health Benefit Exchange created by Section 100500 of the Government Code.~~

~~(g)This section does not exempt a health insurer or a health insurance policy from meeting other applicable requirements of law.~~

~~(h)This section does not prohibit a policy from covering additional benefits, including, but not limited to, spiritual care services that are tax deductible under Section 213 of the Internal Revenue Code.~~

~~(i)Subdivision (a) does not apply to any of the following:~~

~~(1)A policy that provides excepted benefits as described in Sections 2722 and 2791 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-21; 42 U.S.C. Sec. 300gg-91).~~

~~(2)A policy that qualifies as a grandfathered health plan under Section 1251 of PPACA or any binding rules, regulations, or guidance issued pursuant to that section.~~

~~(j)This section shall not be implemented in a manner that conflicts with a requirement of PPACA.~~
~~(k)An essential health benefit is required to be provided under this section only to the extent that federal law does not require the state to defray the costs of the benefit.~~

~~(l)This section does not obligate the state to incur costs for the coverage of benefits that are not essential health benefits as defined in this section.~~

~~(m)An insurer is not required to cover, under this section, changes to health benefits that are the result of statutes enacted on or after December 31, 2011.~~

~~(n)(1)The commissioner may adopt emergency regulations implementing this section. The commissioner, on a one-time basis, may readopt any emergency regulation authorized by this section that is the same as, or substantially equivalent to, an emergency regulation previously adopted under this section.~~

~~(2)The initial adoption of emergency regulations implementing this section and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.~~

~~(3)The initial adoption of emergency regulations implementing this section made during the 2015–16 Regular Session of~~

~~the Legislature and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.~~

~~(4)The commissioner shall consult with the Director of the Department of Managed Health Care to ensure consistency and uniformity in the development of regulations under this subdivision.~~

~~(5)This subdivision shall become inoperative on July 1, 2018.~~

~~(e)This section does not impose on health insurance policies the cost sharing or network limitations of the plans identified in subdivision (a) except to the extent otherwise required to comply with this code, including this section, and as otherwise applicable to all health insurance policies offered to individuals and small groups.~~

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

~~(1)"Habilitative services" means health care services and devices that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology, and other services for people with disabilities in a variety of inpatient or outpatient settings, or both. Habilitative services shall be covered under the same terms and conditions applied to rehabilitative services under the policy.~~

~~(2)(A)"Health benefits," unless otherwise required to be defined pursuant to federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA, means health care items or services for the diagnosis, cure, mitigation, treatment, or prevention of illness, injury, disease, or a health condition, including a behavioral health condition.~~

~~(B)"Health benefits" does not mean any cost-sharing requirements such as copayments, coinsurance, or deductibles.~~

~~(3)"PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.~~

~~(4)"Small group health insurance policy" means a group health insurance policy issued to a small employer, as defined in subdivision (q) of Section 10753.~~

~~SEC. 4.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. State Coverage Requirements of DHM

Table 10. Coverage Requirements of Donor Human Milk by State

State/District	Coverage	Medical Conditions Covered	Outpatient Benefit	Inpatient Benefit	Coverage for Milk Fortifiers
California	Medicaid	Mother and infant have one or more of: 1) Mother unable to breastfeed due to medical conditions, 2) feeding intolerance or medical contraindications to formulas, 3) VLBW and very premature, 4) gastrointestinal anomaly metabolic/digestive disorder, or recovery from intestinal surgery, 5) failure to thrive, 6) infant hypoglycemia, congenital heart disease or pre/post organ transplant, 7) other serious health conditions, 8) mother's milk is contraindicated, unavailable, or available but lacking in quantity/quality.	Silent	Silent	Human-milk derived only
Connecticut	Medicaid	Documented medical necessity. State to adopt or amend regulations for implementation.	Silent	Silent	Silent
District of Columbia	Medicaid	One of: 1) infant is fragile, 2) premature or 3) medically compromised. Mother cannot breastfeed due to illness, death, surgery, chronic condition, drug or medication use. Documented medical necessity. Documented feeding trial every 180 days.	Yes	Yes	Silent
Florida	Medicaid	Infant has one of: 1) birthweight < 1,500 grams, 2) congenital or acquired condition and high risk of feeding intolerance, NEC, or infection, 3) medical indication for a human milk diet.	Silent	Yes	Silent
Illinois	Medicaid + commercial	One of: 1) birth weight <1,500 grams, 2) high risk for NEC, 3) hypoglycemia, 4) congenital heart disease, 5) has or will have an organ transplant, 6) sepsis, 7) other serious congenital or acquired condition for which DHM is medically necessary. Requirements change based on recipient age. If >12 months, recipient must have spinal muscular atrophy.	Yes	Silent	Human milk fortifiers, if indicated by physician
Indiana	Medicaid	Infant has one of: 1) birth weight <1,500 grams; 2) congenital or acquired condition that increases risk of NEC; 3) presence of congenital heart disease; 4) has or will receive organ transplant; 5) congenital or gastrointestinal condition with long-term feeding or malabsorption complications. Requires written order from physician, advanced practice registered nurse, or physician assistant.	Silent	Silent	Silent
Kansas	Medicaid	Critically ill infant in NICU. DHM prescribed by an authorized individual. State determines medical necessity. Milk bank meets state standards.	No	Yes	Silent
Kentucky	Commercial	Prescribed for the prevention of NEC and associated comorbidities. Prescribed by a physician.	Silent	Silent	Human milk fortifiers, if indicated by physician

State/District	Coverage	Medical Conditions Covered	Outpatient Benefit	Inpatient Benefit	Coverage for Milk Fortifiers
Louisiana	Medicaid + commercial	One of: 1) prematurity, 2) malabsorption, 3) feeding intolerance, 4) immunologic deficiency, 5) congenital heart disease, 6) other congenital anomalies, 7) high risk of NEC. Optimal lactation support provided. Education on DHM provided. Milk bank accredited by HMBANA.	No	Yes	Silent
Maine	Medicaid + commercial	Infant has one of: 1) birth weight <1,500 grams; 2) Has a gastrointestinal anomaly or metabolic or digestive disorder or is recovering from intestinal surgery and the infant's digestive needs require additional support; 3) Is not appropriately gaining weight or growing; 4) formula intolerance; 5) hypoglycemia (6) congenital heart disease; (7) received or will receive an organ transplant, 8) Has another serious medical condition for which DHM is medically necessary	Silent	Yes	Silent
Missouri	Medicaid	Critically ill infant in NICU. DHM prescribed by an authorized individual. State determines medical necessity. Milk bank meets state standards.	No	Yes	Silent
New Jersey	Medicaid + commercial	One of: 1) infant unable to receive maternal milk or mother unable to produce or produce sufficient milk, or 2) infant meets any of the following: a) body weight below healthy levels, b) high risk of NEC, c) congenital or acquired condition that may benefit from DHM as determined by the state. Milk bank meets state standards.	Silent	Silent	Human milk fortifiers, if indicated by physician
New York	Medicaid + commercial	One of: 1) <1,500 grams at birth, 2) high risk for NEC, 3) other condition that may benefit from DHM, determined by state.	No	Yes	Human milk fortifiers, if indicated by physician
Ohio	Medicaid	Documented medical necessity.	Yes	Yes	Human milk fortifiers, if indicated by physician
Oregon	Medicaid	Must have all: 1) birth weight <1500 grams or severe underlying gastrointestinal disease; 2) DHM continued through neonatal hospital discharge for medical indications 3) Persistent outpatient medical need 4) maternal breast milk not available or insufficient. Milk bank accredited by HMBANA.	Yes	No	Silent
Pennsylvania	Medicaid	Infant has one of: 1) birth weight <1,800 grams, 2) gestational age ≤32 weeks, 3) high risk of NEC, bronchopulmonary dysplasia, sepsis, or retinopathy of prematurity, 4) congenital or acquired gastrointestinal or other condition associated with long-term feeding or malabsorption complications, 5) congenital heart disease requiring surgery in first year of life, 6) has had/will have organ or bone marrow transplant, or immunologic deficiency, 7) renal disease requiring dialysis in first year of life, 8) infant hypoglycemia or jaundice, 9) neonatal abstinence syndrome, 10) medically necessary as determined by the Pennsylvania Department of Health.	Yes	Yes	Silent

State/District	Coverage	Medical Conditions Covered	Outpatient Benefit	Inpatient Benefit	Coverage for Milk Fortifiers
Texas	Medicaid	Documented medical necessity. Bank meets HMBANA standards or other standards adopted by the state.	Yes	Yes	Silent
Utah	Medicaid	DHM is medically necessary. Mother cannot provide milk.	Yes	No	Silent
Washington	Medicaid + commercial	Infant has one of: 1) birthweight <2,500 grams; 2) gestational age ≤34 weeks; 3) hypoglycemia; 4) risk of NEC, bronchopulmonary dysplasia, or retinopathy of prematurity; 5) congenital or gastrointestinal condition with long-term feeding or malabsorption complications; 6) congenital heart disease requiring surgery in the first year of life; 7) organ or bone marrow transplant; 8) sepsis; 9) congenital hypotonias associated with feeding difficulty or malabsorption; 10) renal disease requiring dialysis in first year of life; 11) craniofacial anomalies; 12) immunologic deficiency; 13) neonatal abstinence syndrome; 14) other serious congenital or acquired condition for which DHM is medically necessary; 15) still inpatient within 72 hours of birth without sufficient human milk available.	Silent	Yes	Silent

Source: California Health Benefits Review Program, 2024; DHCS, 2023; NCSL, 2022; Rose et al., 2022; Florida Statutes §409.906l; 22 Maine Revised Statutes Annotated §3174-III; 24-A Maine Revised Statutes Annotated §4320-V; Pennsylvania Law §443.14; Revised Code of Washington §48.43.815.
Key: AAP = American Academy of Pediatrics; DHM = donor human milk; HMBANA = Human Milk Banking Association of North America; NEC = necrotizing enterocolitis; NICU = neonatal intensive care unit; VLBW = very low birthweight.

Appendix C. Literature Review Methods

This appendix describes methods used in the literature review conducted for this report.

Studies of the effects of donor human milk (DHM) on health outcomes for premature and/or low-birthweight infants were identified through searches of PubMed (MEDLINE) and the Cochrane Library. The search was limited to abstracts of studies published in English. The search was limited to studies published from 2014 to present. 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.

Medical Effectiveness Review

A total of 46 studies were included in the medical effectiveness review for AB 3059,

Medical Effectiveness 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*.[64] 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
- 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* 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.
- *Preponderance of 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.
- *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.
- *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.
- *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.

[64] Available at: www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis.

Search Terms

- Condition/Test Keywords:
  - Breastfeeding/breast feeding
  - Breastmilk/breast milk
  - Humanmilk/human milk
  - Donormilk/donor milk
  - Maternalmilk/maternal milk
  - Mothermilk/mother milk
  - Breastfeed/breast feed
  - Breastfed/breast fed
  - Formulamilk/formula milk
  - Milk banks

AND

- Medical Effectiveness Outcomes:
  - Necrotizing enterocolitis
  - Neurodevelopment
  - NEC
  - Premature infant
  - Very low birth weight infants
  - Extremely low birth weight infants
  - ELBW
  - Infant mortality

Appendix D. Cost Impact Analysis: Data Sources, Caveats, and Assumptions

Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, other approaches may differ between topically similar analyses, and therefore the findings may not be directly comparable. The analysis of AB 3059 was developed using the cost and utilization of donor human milk (DHM) along with offsets for reductions incidence of conditions shown to be prevented or ameliorated by the use DHM. The methodology and results of AB 3059 cost analysis are not comparable to results of prior bills.

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act.
- Per the bill language for AB 3059, Medi-Cal plans are assumed fully compliant with the bill.
- CHBRP surveyed the carriers to determine the percentage of the population with coverage for DHM.
- CHBRP assumed that for members with no benefit coverage, hospitals would provide DHM as needed as part of a maternity bundled payment, without charging the carrier separately or charging the member.

Methodology and Assumptions for Baseline Utilization

Donor human milk and human milk fortifiers

- It was not possible to identify claims for DHM or human milk–derived fortifiers (HMF) in Milliman's proprietary 2022 Consolidated Health Cost Guidelines™ Sources Database (CHSD). It appeared that hospitals do not bill this service separately from other maternity-related services.
- CHBRP estimated baseline utilization for DHM by assuming that all infants hospitalized in newborn intensive care units (NICU) would benefit from receiving supplemental DHM. The utilization rate was calculated from the California birth rate of 11.83 births per 1,000 people as of 2024[65] multiplied by the California percentage of newborns who require NICU care, or 1.1%.[66]
- CHBRP estimated that 30% of newborns receiving DHM also received HMF (Perrin et al, 2018).
- CHBRP estimated that 99% of newborns who would benefit from DHM and HMF receive such services in the baseline period. It is estimated that approximately 13% of hospitals do not currently offer DHM (Boundy et al, 2020), and that 95% of infants requiring such care will be transferred to a hospital that offers this service[67].

Offsets: Necrotizing entercolitis (NEC) and bronchopulmonary dysplasia (BPD)

- CHBRP estimated cost offsets for NEC based on the literature (Buckle and Taylor, 2017).
- CHBRP estimated cost offsets for BPD based on the literature (Johnson et al., 2014).

[65] https://worldpopulationreview.com/state-rankings/birth-rate-by-state
https://www.census.gov/quickfacts/fact/table/CA/PST045222
[66] https://www.cdc.gov/nchs/fastats/birthweight.htm
[67] Communication with V. Flaherman, March 6, 2024.

Methodology and Assumptions for Baseline Cost

- CHBRP assumed an average baseline cost per infant for DHM as $1,000 (Ganapathy et al., 2011). Units utilized per infant range widely. CHBRP assumed that this cost would be borne by the hospital and to be reimbursed through maternity bundled payments rather than billed separately.
- CHBRP assumed an average baseline cost for human milk fortifiers of $10,000 (Ganapathy et al., 2011).
- CHBRP estimated the average cost of treatment for NEC was $119,240.69 (Buckle and Taylor, 2017), trended to 2025.
- CHBRP estimated the average cost of treatment for BPD was $31,506.68 (Johnson et al., 2014), trended to 2025.
- CHBRP applied 5% annual cost trend to these estimates to bring them to 2025 levels.

Methodology and Assumptions for Baseline Cost Sharing

- CHBRP assumed that there is no separate cost sharing for DHM or for HMF.
- CHBRP estimated the average cost sharing for NEC was $148.43 (Buckle and Taylor, 2017), trended to 2025.
- CHBRP estimated the average cost of treatment for BPD was $122.60 (Johnson et al., 2014), trended to 2025.
- CHBRP applied 5% annual cost trend to these estimates to bring them to 2025 levels.

Methodology and Assumptions for Postmandate Utilization

- CHBRP assumed the utilization rate for enrollees would increase postmandate due to wider access to DHM and HMF because of the removal of the tissue bank licensing requirements for hospitals providing DHM. Postmandate, it is assumed that 100% of infants eligible for DHM and HMF will receive the services.

Methodology and Assumptions for Postmandate Cost

- CHBRP assumed the average cost per case of NEC or BPD would not change as a result of AB 3059.

Methodology and Assumptions for Postmandate Cost Sharing

- CHBRP assumed there would be no change in cost sharing as a result of AB 3059.

Methodology and Assumptions related to NEC and BPD

- CHBRP assumed 2.6% of infants requiring NICU care develop NEC, and that this incidence rate can be reduced by 68% if the infant receives DHM (Yang et al., 2020).
- CHBRP assumed that 25% of infants requiring NICU care develop BPD, and this incidence rate can be reduced by 20% if the infant receives DHM (Villamor-Martinez et al., 2018).
- These reduction assumptions apply to all infants receiving DHM in both the baseline and postmandate assumptions.

Variability of Results

Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made in this model. It is almost certain that actual experience will not conform exactly to the assumptions used in this model. Actual amounts will differ from projected amounts to the extent that actual experience is better or worse than expected.

Model and Data Reliance

Milliman has developed certain models to estimate the values included in this report. The intent of the models was to estimate the impact of proposed bill AB 3059. We have reviewed this model, including its inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

The models rely on data and information as input to the models. We have relied upon certain data and information for this purpose and accepted it without audit. To the extent that the data and information provided is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete.

Milliman's data and information reliance includes:

- Data publicly available from the California Department of Managed Healthcare, California Department of Insurance, CalPERS, and other official state organizations
- Population and other metrics prepared for use in this model by CHBRP, and
- All sources mentioned above in the Analysis-Specific Caveats and Assumptions section.

The models, including all input, calculations, and output may not be appropriate for any other purpose.

We have performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review was beyond the scope of our investigation.

Qualifications to Perform Analysis

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. The developer of this model and author of this paper is a member of the American Academy of Actuaries and meets the qualification standards for performing the analyses supported by this model.

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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, **Milliman**, 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.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at **www.chbrp.org**.

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