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MANDATED BENEFIT REVIEW OF HOUSE BILL 1106 AND SENATE BILL 717

SUBMITTED TO THE 192<sup>ND</sup> GENERAL COURT:

# **AN ACT RELATIVE TO HUMAN DONOR MILK COVERAGE**

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Prepared for Massachusetts Center for Health Information and Analysis

By Berry Dunn McNeil & Parker, LLC

# Mandated Benefit Review of House Bill (H.B.) 1106 and Senate Bill (S.B.) 717 Submitted to the 192<sup>nd</sup> General Court

## An Act Relative to Human Donor Milk Coverage

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## LIST OF ACRONYMS

AAFP	American Academy of Family Practice
AAP	American Academy of Pediatrics
ACOG	American College of Obstetricians and Gynecologists
APCD	All-Payer Claims Database
BMDF	Bovine (Cow) Milk-Derived Fortifier
BPD	Bronchopulmonary dysplasia
CDC	U.S. Centers for Disease Control and Prevention
CHIA	Massachusetts Center for Health Information and Analysis
DHM	Donor Human Milk/Pasteurized Human Donor Milk
EHMD	Exclusive Human Milk Diet – mother’s and/or donor milk, and human milk-derived fortifier
HMBANA	Human Milk Banking Association of North America
HMDF	Human-Milk-Derived Fortifier
HMD	Human Milk Diet – may include mother’s own milk and/or donor milk
HMO	Health Maintenance Organization
LBW	Low birthweight <2,500 grams
LOS	Late-onset sepsis
MMBNE	Mothers' Milk Bank Northeast
NEC	Necrotizing enterocolitis
NICU	Neonatal Intensive Care Unit
PMPM	Per-Member-Per-Month
ROP	Retinopathy of prematurity
VLBW	Very low birthweight <1,500 grams
WHO	World Health Organization

# 1.0 Benefit Mandate Overview: H.B. 1106 and Senate Bill 717; Both Entitled: An Act Relative to Human Donor Milk Coverage

## 1.1 History of the Bill

The Massachusetts Legislature's Committee on Health Care Financing referred House Bill (H.B.) 1106 and Senate Bill (S.B.) 717, both titled, "An Act Relative to Human Donor Milk Coverage,"<sup>1</sup> to the Massachusetts Center for Health Information and Analysis (CHIA) for review. Massachusetts General Law (MGL) Chapter 3 §38C requires CHIA to review the medical efficacy of treatments or services included in each mandated benefit bill referred to the agency by a legislative committee, should it become law. CHIA must also estimate each bill's fiscal impact, including changes to premiums and administrative expenses.

This report references H.B.1106 and S.B. 717 together and hereafter as "the bills." This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth of Massachusetts (Commonwealth) defrayal under the Affordable Care Act (ACA), nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

## 1.2 What Does the Bill Propose?

As submitted to the 192<sup>nd</sup> General Court of the Commonwealth of Massachusetts, the bills require health insurers to cover pasteurized donated human breast milk (DHM), including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health.

The bills specify the eligibility for coverage of DHM for infants that meet criteria summarized in Items 1, 2, and 3, below:

1. The covered person is an infant under the age of six months; **and**
2. The milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health; **and**
3. A licensed medical practitioner has issued a written order for the provision of such human breast milk for an infant who meets any of the criteria in 3a, 3b, or 3c below:
  - a) Is medically or physically unable to receive maternal breast milk or participate in breastfeeding; **or**
  - b) Whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support; **or**
  - c) Meets any of the following conditions:
    - i. A body weight below healthy levels determined by the licensed medical practitioner; **and/or**
    - ii. A congenital or acquired condition that places the infant at a high risk for development of necrotizing enterocolitis; **and/or**

- iii. A congenital or acquired condition that may benefit from the use of such human breast milk as determined by the Department of Health.

### 1.3 Medical Efficacy of the Bill

Use of DHM shows medical efficacy for use with infants born at low birthweight and with other specific medical conditions, until they are healthy enough for discharge from the hospital. The cost for the covered benefit for these infants is relatively small. Most of the cost impacts of the bills accrue for out-of-hospital infants through six months of age that are eligible under maternal factors rather than for medical, for whom the use of DHM does not have well-established medical efficacy.

### 1.4 Current Coverage

BerryDunn surveyed 10 insurance carriers in the Commonwealth, and six responded. None of these carriers currently offer coverage of DHM in their commercial insurance plans. One plan noted that currently it would only consider coverage for MassHealth (Medicaid) under the federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirement(s). If such coverage were needed, this plan noted that it would look to the American Academy of Pediatrics (AAP) policy on the use of DHM as a guide.

### 1.5 Cost of Implementing the Bill

The estimated impact of the proposed requirement on medical expense and premiums appears below. The analysis includes development of a best estimate “mid-level” scenario, as well as a low-level scenario, and a high-level scenario using more conservative assumptions. The impact on premiums is driven by the provisions that carriers cover DHM and human-milk-derived fortifiers (HMDF), and these costs are offset by the reduction in costs in use of enteral formulas. Variation between scenarios is attributable to the uncertainty surrounding the number of infants potentially receiving the covered benefit and length of time that each infant will require DHM and HMDF.

A relatively small number of VLBW and LBW infants are born annually, and these infants depend on fortifiers for relatively short time periods. The covered benefit for medically needy in-hospital infants accounts for only 2% of the bill’s estimated marginal premium cost in the mid-scenario. Coverage under maternal factors (apart from medical need of infant) for infants up to six months of age may extend coverage to a potentially larger number of eligible infants, accounting for 98% of the projected claims cost in the mid scenario. The bill extends coverage to out-of-hospital infants, through age six months, based on a potentially wide range of maternal factors -- possibly funding DHM as a substitute for formula for a large number of healthy infants.

**Error! Reference source not found.**ES-1 displays the effect on claims cost of each of the component parts for the first year, 2023. **Error! Reference source not found.**ES-2 summarizes the estimated effect of the bill on premiums for fully insured plans over five years. The bill, if enacted as drafted, could increase fully insured premiums by as much as 0.976% on average over the next five years; a more likely increase is around 0.731%, equivalent to an average annual expenditure of \$116.5 million over the period 2023 – 2027. The impact on premiums includes the requirement that carriers cover DHM and HMDF; coverage for maternal factors for infants under six months of age drives most of the premium increase.

**Table ES-1. Projected PMPM Claims Cost and Total Cost by Component, 2023**

	LOW	MID	HIGH
Projected PMPM Claims Cost, 2023			
Donor Human Milk – LBW and NEC infants	\$0.01	\$0.02	\$0.03
Human Milk-Derived Fortifier for LBW infants	\$0.04	\$0.05	\$0.07
Donor Human Milk -- Months 1 – 6 based on maternal criteria	\$2.33	\$3.50	\$4.67
Offset – Reduction in payments for enteral formula	<\$0.01 >	<\$0.01 >	<\$0.01 >
<b>Total Projected PMPM Claims Cost, 2023</b>	<b>\$2.37</b>	<b>\$3.57</b>	<b>\$4.76</b>
Total Projected Cost by Component, 2023			
DHM – LBW and NEC infants	\$277,888	\$555,777	\$833,665
H MDF – LBW infants	\$913,410	\$1,370,115	\$1,826,820
DHM – months 1 – 6 based on maternal criteria	\$58,204,356	\$87,306,534	\$116,408,712

**Table ES-2. Summary Results**

	2023	2024	2025	2026	2027	WEIGHTED AVERAGE	FIVE- YEAR TOTAL
Average Members (000s)	2,156	2,242	2,262	2,266	2,269		
Medical Expense Low (\$000s)	\$44,224	\$65,050	\$66,946	\$68,381	\$69,834	\$66,458	\$314,435
Medical Expense Mid (\$000s)	\$66,528	\$97,863	\$100,721	\$102,886	\$105,078	\$99,987	\$473,076
Medical Expense High (\$000s)	\$88,832	\$130,677	\$134,496	\$137,391	\$140,323	\$133,517	\$631,718
Premium Low (\$000s)	\$51,508	\$75,764	\$77,972	\$79,643	\$81,336	\$77,403	\$366,223
Premium Mid (\$000s)	\$77,485	\$113,982	\$117,310	\$119,831	\$122,385	\$116,455	\$550,993
Premium High (\$000s)	\$103,463	\$152,199	\$156,647	\$160,019	\$163,434	\$155,508	\$735,763
PMPM Low	\$2.76	\$2.82	\$2.87	\$2.93	\$2.99	\$2.88	\$2.88
PMPM Mid	\$4.15	\$4.24	\$4.32	\$4.41	\$4.49	\$4.33	\$4.33
PMPM High	\$5.55	\$5.66	\$5.77	\$5.89	\$6.00	\$5.79	\$5.79
Estimated Monthly Premium	\$562	\$577	\$593	\$609	\$625	\$593	\$593
Premium % Rise Low	0.491%	0.488%	0.484%	0.481%	0.478%	0.486%	0.486%
Premium % Rise Mid	0.739%	0.734%	0.729%	0.724%	0.719%	0.731%	0.731%
Premium % Rise High	0.987%	0.980%	0.973%	0.966%	0.960%	0.976%	0.976%

Note: Figures in Table ES-2 differ from Table ES-1 because ES-1 reflects dollars based on a membership snapshot used in the development of the PMPMs. Table ES-2 displays projected membership based on a population projection. Table ES-2 also applies a 72% adjustment factor to the first year (2023) of implementation to account for ramp up in implementation.



## 1.6 Plans Affected by the Proposed Benefit Mandate

The bill amends statutes that regulate health insurance carriers in the Commonwealth. It includes the following sections, each of which addresses statutes regarding a particular type of health insurance policy when issued or renewed in the Commonwealth:<sup>2</sup>

- Chapter 32A – Plans Operated by the Group Insurance Commission (GIC) for the Benefit of Public Employees
- Chapter 175 – Commercial Health Insurance Companies
- Chapter 176A – Hospital Service Corporations
- Chapter 176B – Medical Service Corporations
- Chapter 176G – Health Maintenance Organizations (HMOs)

The bill, as written, amends Chapter 118E of the General Laws. However, estimating the bill's impact to MassHealth membership is outside the scope of this report.

## 1.7 Plans Not Affected by the Proposed Benefit Mandate

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or insurer to provide only administrative functions), except for those provided by the GIC, are not subject to state-level health insurance mandates. State mandates do not apply to Medicare and Medicare Advantage plans or other federally funded plans, including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employees Health Benefit Plan, the benefits for which are determined by, or under the rules set by, the federal government.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth of Massachusetts (Commonwealth) defrayal under the Affordable Care Act (ACA), nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

## Endnotes

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<sup>1</sup> The 192<sup>nd</sup> General Court of the Commonwealth of Massachusetts, House Bill 1106 and Senate Bill 717, “An Act Relative to Human Donor Milk Coverage.” Accessed July 29, 2022: <https://malegislature.gov/Bills/192/H1106> and <https://malegislature.gov/Bills/192/S717>.

<sup>2</sup> Although Chapter 176A is not included in the bill’s current language, the sponsor confirmed the bill’s intent is to include it. Chapter 118E (MassHealth) is included in the bill, but estimating the bill’s impact for MassHealth is not within the scope of this report.

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# AN ACT RELATIVE TO HUMAN DONOR MILK COVERAGE

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MEDICAL EFFICACY ASSESMENT

## 1.0 Executive Summary

House Bill (H.B.) 1106 and Senate Bill (S.B.) 717, both titled “An Act Relative to Human Donor Milk Coverage,” (hereafter “the bills”) require health insurance carriers to cover pasteurized donated human breast milk (DHM), including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health. The bill designates criteria for infants eligible to receive the covered benefit. Several criteria generally correspond to the recommended uses for DHM, with medical efficacy established by systematic reviews of the literature. One of the criteria for coverage inclusion lacks established medical efficacy.

The medical benefits are well established for use of DHM, instead of infant formula specifically for very low-birthweight babies (weight less than 1,500 grams) when mother’s own milk is not available or sufficient. The benefits of DHM for VLBW infants include a decreased risk for necrotizing enterocolitis (NEC — a severe gut disorder that occurs most often in premature infants); late-onset sepsis; chronic lung disease; retinopathy of prematurity; and neurodevelopmental impairment.<sup>1</sup>

Overall, the medical efficacy findings pertain to a particular group of infants with specific medical need. The bills reference such medical need by the infant in provisions iii(a) and iii(c), when mother’s own milk is not available. The other independent eligibility criteria designated by iii(b); for infants with mothers “medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support” allows eligibility for infants under a much wider range of reasons. This component does not require other related need by the infant, which may extend this covered benefit to otherwise healthy babies whose families believe that they are better off consuming human milk than formula. Evidence does not clearly support the medical efficacy of DHM for the general population of otherwise healthy infants when the mothers are unable to lactate or unable to produce sufficient milk supply for their infants. In those cases, absent specific medical need by the infant, formula provides an acceptable alternative for feeding.<sup>2</sup>

When mother’s own milk is unavailable or insufficient, DHM supplemented with a multi-nutrient fortifier is the first recommended alternative for infants with VLBW.<sup>3</sup> VLBW infants often need additional fortifiers to supplement human milk, to support their growth and neurodevelopment. Neonatal intensive care units (NICUs), as standard practice, use mother’s or donor human milk with the addition of bovine-milk-derived fortifier.

The bill’s language requires insurance coverage of “human milk fortifiers.” This could be interpreted to mean fortifiers of DHM that would include human-milk-derived fortifiers or bovine-milk-derived fortifier — both of which may carry the label “human milk fortifier”<sup>4</sup> — or the bill could refer to solely requiring coverage of human-milk-derived fortifiers. While human-milk-derived fortifiers have demonstrated medical efficacy, they do not appear to have advantages in comparative effectiveness over current use of bovine-milk-derived fortifiers.<sup>5</sup> The use of human milk-derived fortifiers remains limited due to its substantial cost and a relatively weak evidence basis.<sup>6</sup> Nonprofit milk banks do not provide fortifiers, which are sold separately by for-profit distributors that market their own proprietary human milk fortifiers that may include additional ingredients. Overall, evidence supports the medical efficacy of both bovine-milk-derived and human-milk-derived fortifiers when used with donor human milk.

## 2.0 Medical Efficacy Assessment

MGL Chapter 3 §38C charges CHIA with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the treatment or service and describe the potential impact of a mandated benefit on the quality of patient care and health status of the population.

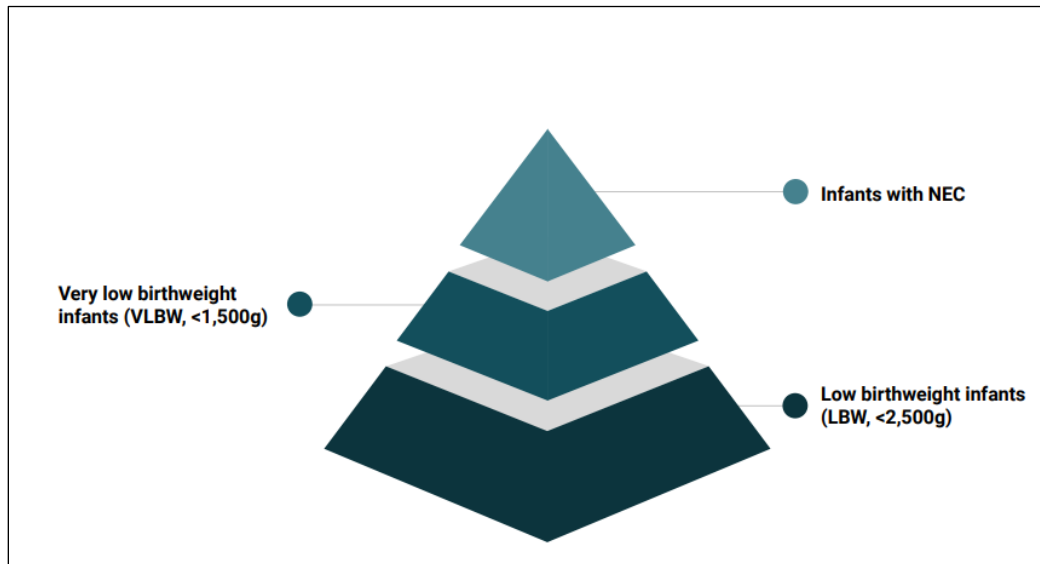
The medical efficacy assessment relied on the following sources of data:

- Published scholarly literature, reports, and population-based data, cited throughout this report.
- Survey of commercial carriers in the Commonwealth of Massachusetts to gather descriptions of current coverage.
- Interviews (via email questioning and teleconference) with:
  - Dr. Margaret Parker, MD, MPH; a neonatologist at the University of Massachusetts Memorial Medical Center in Worcester and the lead author of the recent American Academy of Pediatrics statement on human milk for VLBW infants. She has a scholarly research background related to breastfeeding and human milk, including DHM, with dozens of papers published in peer-reviewed journals.
  - Dr. Sarah Taylor; a neonatologist at Yale University School of Medicine, a Professor of Pediatrics (Neonatal-Perinatal Medicine) and Director of Clinical Research, Pediatrics, and a recognized authority on breastfeeding and use of DHM.
  - Deborah Youngblood, PhD, Executive Director, Mothers' Milk Bank Northeast, a member of Human Milk Banking Association of North America (HMBANA), located in Newton, Massachusetts.
  - Legislative sponsors, providing information about the intended effect of the bill.
- Massachusetts all-payer claims database (APCD)

### 2.1 Eligibility for Coverage: When is DHM Medically Necessary?

The AAP, in its 2021 policy statement, recommends the provision of pasteurized donor human milk (DHM), appropriately fortified, for hospitalized VLBW (weight below 1,500 grams) infants in the NICU, when mother's own milk is not available or sufficient.<sup>7</sup> This recommendation corresponds with several of the elements delineated in the bill for coverage of DHM. Figure 1 displays the potential population of preterm infants that would qualify under the medical necessity criteria.

**Figure 1. Infants with Medical Necessity for DHM\***



*\*Other infants with specific medical conditions will also qualify on a case-by-case basis, including after gut surgery, after cardiac surgery or with other rare, severe feeding intolerance.<sup>8</sup>*

However, in 3b, the bill specifies “[infants] whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support,” preceded by “or,” which allows broader eligibility independent of any medically indicated need by the infant. This provision, without requiring other related need by the infant, may open eligibility for this covered benefit to otherwise healthy babies whose families believe that they are better off consuming human milk than formula.

A wide range of reasons—medical and otherwise—may render mothers unable to lactate at all or sufficiently to meet their babies’ needs.<sup>9</sup> Mothers’ medical issues that may impede breastfeeding include having had a premature labor or a C-section,<sup>10</sup> a mastectomy,<sup>11</sup> a breast reduction surgery,<sup>12</sup> taking contraindicated drugs,<sup>13</sup> having inverted nipples or other nipple malformations,<sup>14</sup> having an infectious disease transmissible through milk,<sup>15</sup> experiencing breast pain or mastitis,<sup>16</sup> or having insufficient milk.<sup>17</sup> Other reasons some mothers cannot breastfeed — or that may affect a mother’s ability to produce milk — include stress, abuse, lack of social or emotional support, that they are adoptive parents, and/or they find their employment incompatible with successful and long-term breastfeeding.<sup>18,19</sup> Mothers who work in lower paying jobs may have less or no leave, following birth, to support breastfeeding initiation.<sup>20</sup> They may have little or no opportunity or support for breastfeeding/pumping at work, which requires a clean and safe place to pump and refrigerate milk.

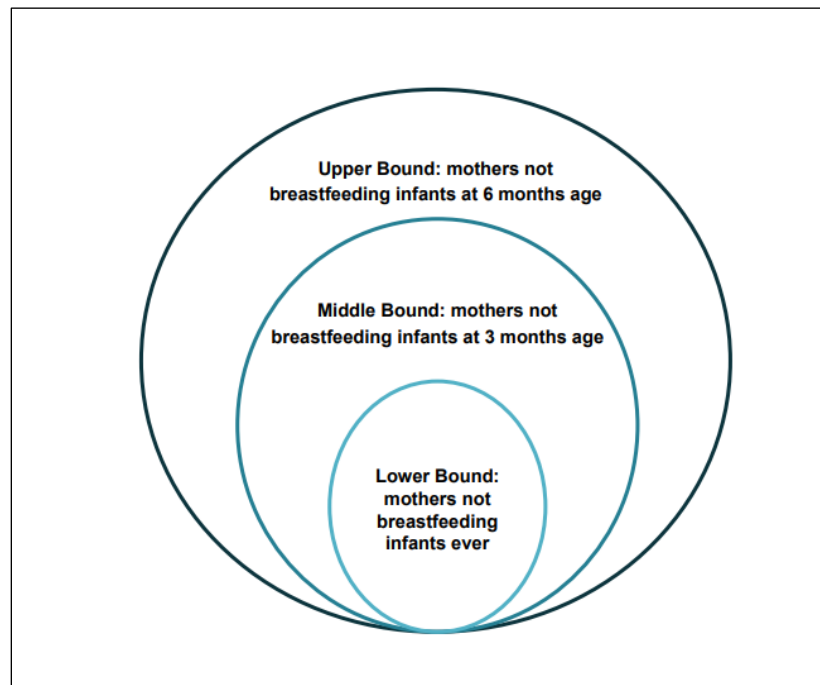
Figure 2 displays the potential population of mothers with commercial insurance that would qualify under the bill based on total annual Massachusetts births and the CDC reports of mothers breastfeeding infants at birth and at six months of age.<sup>21</sup> (The figures exclude mothers with self-insured plans, who are not affected by state-level coverage mandates.) The bill also requires DHM coverage by Medicaid (MassHealth). This would reach mothers and infants with low incomes who currently rely on (federally funded) formula vouchers from the Women Infants and Children (WIC) nutrition program to pay for the cost of formula.<sup>22</sup>

The Academy of Family Practice (AAP), the U.S. Centers for Disease Control and Prevention (CDC), and other medical professional statements promote feeding with human milk through six month's age recognize that formula feeding may often provide an acceptable alternative for feeding healthy babies.<sup>23</sup> The provision of DHM may be preferred even for healthy infants when the mother is unable to lactate sufficiently. However, the provision of DHM as a substitute for formula to the broader population of healthy babies would require a potentially much larger supply of DHM than might be available.<sup>24</sup>

Currently, the Mothers' Milk Bank Northeast (MMBNE) — a nonprofit milk bank member of the HMBANA and supplier to the Commonwealth of Massachusetts — reports providing over 90% of its DHM supply to hospitals for high-need infants and is able to offer only a limited quantity, for a few weeks, to mothers in an outpatient setting in the community.<sup>25</sup> MMBNE considers provision of its product to serve as a “bridge to breastfeeding” rather than as a substitute for formula. For mothers who are unable to lactate at all, or sufficiently after a few weeks post-discharge from the hospital, MMBNE does not typically sustain long-term reliance on DHM and instead assists with transition to formula feeding.<sup>26</sup>

Nonprofit milk banks generally provide priority access for DHM to medically vulnerable infants, and hospitals that use DHM have various processes to guide allocation of limited supply.<sup>27</sup> During the formula shortage in 2022, milk banks received unprecedented levels of requests for DHM, exceeding the requests for the preterm infants they typically serve.<sup>28</sup> Families who have healthy full-term babies would not qualify for a prescription for DHM, but were able to request a small amount (up to 40 ounces) of DHM from banks. The DHM available in milk banks in the U.S. is currently not enough to account for the lack of formula in stores.<sup>29</sup>

**Figure 2. Potential Population of Mothers Qualifying under the Bill**



## 2.2 Medical Necessity: Other States' Coverage

Some other states require private health insurance and/or Medicaid to cover the costs of DHM. These experiences in other states provide varying perspectives of when DHM is medically necessary.

As of 2022, 14 states and Washington D.C. have enacted DHM legislation or DHM regulations pertaining to Medicaid or commercial insurance.<sup>30</sup> (See Appendix A). The legislation and regulations for DHM vary widely, with differing age limits and recipient mother eligibility criteria. All require a prescription for DHM by a licensed healthcare provider and documentation of medical necessity.<sup>31</sup> Although the definitions of medical necessity vary, states typically require that the provider explain why the infant cannot survive and thrive on formula and that the mother cannot provide breast milk for the infant.

Appendix A summarizes state policies pertaining to public and commercial insurance coverage for DHM. Four states—Illinois, Kentucky, New Jersey, and New York—have laws pertaining to commercial coverage of DHM, each with differing eligibility criteria.<sup>32</sup> New Jersey's eligibility for coverage provisions is identical to those proposed for Massachusetts.

The Oregon Center for Evidence-Based Policy, in 2017, examined DHM policies for 10 private payers, and found none stating coverage of DHM, and 3 explicitly stating exclusion of DHM from coverage.<sup>33</sup> Two other plans listed banked breast milk on their excluded products in their oral formula and nutritional support policies. AmericaHealth Caritas—a national insurance carrier operating in nine states and Washington D.C. that includes a pharmacy benefits manager and a specialty pharmacy—identifies the use of DHM as clinically proven and medically necessary only if the following criteria are met:<sup>34</sup>

- Infant is at risk for developing NEC, meeting one of the following:
  - VLBW equal to or less than 1,500 grams
  - Infant was born at or prior to 28 weeks of gestation and is under 6 months
- Infant has a gastrointestinal anomaly, metabolic or digestive disorder, or is in recovery from intestinal surgery that requires additional support
- Infant is at risk for malabsorption, *and*
- The mother's breast milk is either contraindicated or unavailable

Some advocates have called for coverage of infants through two years of age who have documented medical necessity for human milk and coverage for patients in both inpatient and outpatient settings.<sup>35</sup>

## 2.3 Medical Efficacy Studies

This efficacy review focuses on the degree to which the use of DHM achieves a specific projected outcome for a specific medically indicated purpose. Substantial literature addresses how breastfeeding (and, human milk, generally) may offer various benefits for all infants.<sup>36</sup> While infant formula stands recognized as an acceptable alternative for feeding for healthy infants, DHM could also substitute in cases when healthy infants might not have access to mothers' own milk. For the general population of otherwise healthy infants—lacking specific medical need—



breastfeeding is generally recommended. But when the mothers are unable to lactate or unable to produce sufficient milk supply for their infants, infant formula is recognized as an acceptable alternative and evidence does not demonstrate specific benefits of DHM, which differs in composition from human milk from breastfeeding due to having been pasteurized.<sup>37,38</sup>

Focusing on preterm or LBW infants, a 2019 systematic review assessed the existing evidence to determine the effect of feeding with formula compared with DHM on growth and development.<sup>39</sup> The review assessed effects on digestion, growth, and the risk of severe bowel problems. Preterm infants fed with DHM, rather than with an artificial formula experience, reduced risk of necrotizing enterocolitis (NEC), a severe gut disorder that occurs most often in premature infants. DHM, compared to formula, is associated with slower rates of infant growth during the hospital stay of VLBW infants, indicating a need for additional fortifiers.<sup>40,41</sup> However, the growth deceleration does not appear to adversely affect neurodevelopmental outcomes, survival, or longer-term growth and development.<sup>42</sup>

The use of human milk products (preterm formula and fortifiers) has been shown to lead to significant clinical benefits for very low birth weight (VLBW) babies.<sup>43</sup> However, studies vary in the specifications in two regards:

- 1) Infant birthweight specified for measurable benefits, with some showing positive effects for infants with birthweights below 1,250 grams<sup>44,45,46,47,48,49,50,51</sup> and others showing benefits for infants up to 1,500 grams<sup>52,53,54,55</sup>
- 2) Whether infants receive an exclusive human milk diet (EHMD) of both DHM and human milk-derived fortifier (HMDF), or studies specify use of DHM, and may use bovine milk-derived fortifiers (BMDFs)

DHM—apart from the fortifier consideration—is particularly noted for its protective effects against NEC. NEC is one of the most significant causes of morbidity and mortality in preterm infants, with 90% of cases occurring in newborns less than 32 weeks of gestation, and affecting approximately 6% – 10% of the infants with VLBW.<sup>56</sup> A systematic review of the literature, published in 2020, reports protective effects of different doses of DHM on NEC, concluding that exclusive human milk and partial human milk reduced the incidence of NEC in premature infants, especially in those fed with a high proportion of human milk.<sup>57</sup>

A 2019 systematic review examined reported outcomes from 12 studies comparing formula to DHM in the feeding of preterm or LBW infants.<sup>58</sup> The conclusion: Formula feeding, either as a supplement to breast milk or as a sole food source, corresponds to a higher risk of developing NEC. This review did not find evidence of formula versus DHM on survival, or longer-term growth and development, and formula-fed infants did experience higher rates of weight gain, linear growth, and head growth. The 2018 version of this systematic review, assessing eleven studies, also reported that formula feeding increased incidence of NEC, although formula-fed infants had higher in-hospital weight increase, length, and head circumference.<sup>59</sup>

Another 2018 systematic review assessed the post-1990 literature addressing a range of outcomes, including NEC, late-onset sepsis (LOS), retinopathy of prematurity (ROP), bronchopulmonary dysplasia (BPD) and neurodevelopment.<sup>60</sup> The studies included infants born at or before 28 weeks gestation and/or with infant mean birth weight below 2,500 grams (VLBW). This review reported DHM's protective effect against NEC, with an approximate 4% reduction in incidence of NEC among infants receiving DHM. DHM also provided a possible reduction in LOS, severe ROP, and severe NEC. The review also concludes that, particularly for NEC, any volume of DHM is better than exclusive preterm formula, and the higher the dose of DHM, the greater the protection observed.<sup>61</sup> However, another 2018 meta-analysis of available studies addressed whether DHM offered protective effects for the risk of the most severe cases on NEC only—those requiring surgery.<sup>62</sup> This study concluded that DHM does not exert a clear protective effect on surgical cases of NEC compared with preterm formula.

A 2017 report published by the Oregon Center for Evidence-Based Policy examined the effectiveness and policies of DHM for LBW infants.<sup>63</sup> The report identifies what it rates as “moderate strength” evidence that DHM helps prevent NEC, and “low strength” evidence that DHM increases maternal breastfeeding at NICU discharge or that it could result in slower short-term growth.<sup>64,65</sup> The Oregon report identifies moderately strong evidence that the use of DHM does not significantly change neurodevelopmental outcomes, and low strength of evidence that DHM changes the risk of death or of ROP.<sup>66</sup> For example, a 2016 study reports that use of supplemental DHM, compared with formula for VLBW infants, did not improve neurodevelopment at 18 months' age.<sup>67</sup>

More recent studies more clearly establish the neuroprotective effect of human milk diets (both mother's own milk and DHM) in VLBW infants,<sup>68</sup> despite slower weight gain during a NICU stay, showing that infants who received human milk in the NICU show positive outcomes at two years of age.<sup>69,70</sup> A 2021 study reports an independent neuroprotective effect of human milk diets on extremely low-birthweight infants (ELBW, <1,000 grams), along with decreased incidence of severe intraventricular hemorrhage or periventricular leukomalacia.<sup>71</sup> Other more recent published literature has strengthened the evidence specifically related to DHM.<sup>72</sup> A 2021 systematic review concludes:

*“Provision of mother’s own milk for hospitalized very low birth weight (VLBW) ( $\leq 1,500$  grams) infants in the NICU provides short- and long-term health benefits. Mother’s own milk, appropriately fortified, is the optimal nutrition source for VLBW infants. Every mother should receive information about the critical importance of mother’s own milk to the health of a VLBW infant. Pasteurized human donor milk is recommended when mother’s own milk is not available or sufficient.”<sup>73</sup>*

Dr. Margaret Parker — a neonatologist at the University of Massachusetts Memorial Medical Center in Worcester and the lead author of the recent American Academy of Pediatrics statement on human milk for VLBW infants — provides the following points of summary:<sup>74</sup>

- Current practice in U.S. NICUs focuses on use of human milk for infants <34 weeks or 1,500 – 2,000 grams and, after that point, infants in the hospital typically transition to preterm formula. The AAP statement on DHM focuses on infants with birthweight <1500 grams.
- Human milk is better for the gut, and infants may benefit from continued longer-term use, but studies are limited that indicate medical efficacy or need. There are case reports and small studies indicating use for infants with specific medical conditions, such as after gut surgery, after cardiac surgery or other rare, severe feeding intolerance.
- With regard to the six-month provision in the bill: Some infants with particular medical conditions will require longer-term use of DHM, but this is not a general medical recommendation for all preterm infants.

## 2.4 Medical Efficacy: Human Milk Fortifiers

The bill, in addition to requiring the provision of pasteurized donated human breast milk, requires coverage for “human milk fortifiers if indicated in a medical order provided by a licensed medical practitioner.” This language could be interpreted to mean coverage for fortifiers of DHM that would include HMDF or BMDF — both of which may carry the label “human milk fortifier”<sup>75</sup> — or the bill could refer to solely requiring coverage of HMDF.

The use of fortifiers, in addition to mother's or donor milk, provides essential nutrients for many preterm infants to support growth and decrease neurodevelopmental delay.<sup>76,77</sup> Preterm infants fed DHM may receive either BMDF or HMDF. Both are generally considered effective, with rigorously designed studies comparing the two approaches finding no difference in feeding tolerance, morbidity, and mortality.<sup>78,79</sup>

Reports about the comparative effectiveness of HMDF over BMDF are mixed, with much of the work observational and lacking a well-constructed comparison group. Several individual studies seem to suggest a benefit in morbidity and mortality when babies are fed an EHMD, including HMDF, leading to a reduction of costs.<sup>80,81,82</sup> Some studies also report an increase in adverse outcomes with BMDF, compared to the use of HMDF, including development of

NEC and severe morbidity comprising NEC surgery or death.<sup>83,84,85,86,87</sup> Such studies, however, often compare an EHMD to infants receiving formula (bovine-based) along with BMDF rather than with infants receiving mother's or DHM along with BMDF.

A systematic review of the literature, published in 2020, deems reported differences between use of HMDF and BMDF not significant after excluding studies with high risk of bias.<sup>88</sup> This 2020 systematic review concludes that the evidence to date is low quality and awaits well-designed randomized control trials (RCTs) without the influence of industry. The authors also note that newer BMDF (hydrolyzed to break down proteins) may help in achieving optimal growth without increasing the risk of NEC and that BMDF offers benefits in that it is readily available at a relatively low cost compared with HMDF.

A 2019 systematic review of the literature also compared the use of HMDF to BMDF in measures of mortality, morbidity, growth, and development in preterm infants.<sup>89</sup> The conclusion: HMDF does not decrease the risk of NEC in exclusively breast-milk-fed preterm infants and did not improve growth nor decrease feeding intolerance, late-onset sepsis, or death. The review also notes that most studies contain weakness in methodological quality, and evidence overall remains insufficient.

A recently, frequently cited randomized control trial—comparing the efficacy of HMDF to BMDF in the absence of formula—reports no difference in feeding tolerance, postnatal growth, and morbidity.<sup>90</sup> The conclusion: an EHMD—mother's or donor milk with HMDF—presents clear advantages when compared to feeding with artificial formula. But evidence does not establish the beneficial effects of HMDF over BMDF as fortifiers with DHM.

A 2020 paper reports the routine use of DHM in 88% of Level 3 and 4 NICUs (responding to a survey), but far fewer (44% of responding NICUs) reporting use of HMDF.<sup>91</sup> The use of HMDF shows an increase from a 2015 study, which reported use of HMDF by about 20% of NICUs in the U.S.<sup>92</sup> The relatively high price for the product, and lack of insurance coverage, have deterred hospitals from adopting use of HMDF.<sup>93</sup> The expansion of insurance coverage for this product would remove this barrier for hospitals, and may increase expectations for HMDF use by parents of infants in the NICU.<sup>94</sup> Nonetheless, the published literature suggests limited data to support the use of HMDF instead of BMDF. A 2018 review notes the need “to evaluate the benefit-risk ratio, particularly as these products are very expensive and use large amounts of donated milk to make the fortifier, which could be used more directly to feed preterm babies.”<sup>95</sup>

BerryDunn conducted interviews with two perinatologists with recognized expertise and published work about the use of DHM and HMDF. Dr. Sarah Taylor, a neonatologist at Yale and a co-author of several studies addressing the use of fortifiers,<sup>96</sup> did not endorse the use of HMDF, asserting that the evidence basis remains weak, and does not justify the expense relative to bovine-based fortifier.<sup>97</sup> Dr. Margaret Parker, the lead author of the recent AAP statement on human milk for VLBW, summarizes the points as follows.<sup>98</sup>

- The existing literature is mixed about the medical efficacy of HM-derived fortifiers, with the O'Connor study providing the most robust design and demonstrating no difference in feeding tolerance between use of HM-derived and BM-derived fortifiers.
- BM-derived fortifiers are less costly and newer hydrolyzed versions that break down proteins are thought to be less disruptive to the infant gut.
- The AAP statement did not make a recommendation on the use of HDMF because of the mixed evidence and substantial increase in price. Most states with donor milk legislation have not endorsed human milk fortifiers.

## 2.5 Cost-Effectiveness

Several studies address the cost-effectiveness of DHM and HMDF. An exclusive human milk diet (EHMD) using human-milk-based products (preterm formula and fortifiers) is higher cost relative to diets that include cow's-milk-based products.<sup>99</sup>

Prolacta markets its milk products to hospitals through a cost-benefit analysis.<sup>100</sup> The company asserts overall costs savings specifically for VLBW infants weighing between 500 and 1,250 grams and compares the costs of the fortifier against NICU care for prematurity-related morbidities and interventions, including necrotizing enterocolitis (NEC) and surgical NEC.<sup>101</sup> In one study cited by Prolacta, EHMD resulted in 4.5 fewer days of hospitalization and an average of \$27,388 cost savings per VLBW infant.<sup>102</sup> The National Association of Neonatal Nurses (NANN), also reviewed the range of health benefits associated with DHM for vulnerable infants, both during the hospital stay and following discharge, and concluded that every dollar spent on banked DHM can save up to \$11 in other medical costs.<sup>103,104</sup>

Existing literature addresses the cost-effectiveness of DHM for VLBW infants. Studies suggest that DHM substantially reduces mortality and improves other health outcomes, generating substantial cost savings by reducing adverse clinical events.<sup>105,106</sup> A recent systematic review of published full economic evaluations of DHM versus standard feeding in infants in the NICU settings concludes that DHM interventions are cost-saving.<sup>107</sup>

Important to note: while all of the studies focus on the use of DHM, the studies vary with their use of fortifiers—human-milk-based or bovine-based—in attaining their cost-effectiveness estimates. Further, these findings point to the medical efficacy and cost-effectiveness of DHM for a particular group of infants with specific medical need. The bill references such medical need by the infant in provisions iii(a) and iii(c), when mother's own milk is not available. The other independent eligibility criteria designated by iii(b); for infants with mothers "medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support" allows eligibility for infants under a much wider range of reasons and may substantially expand the number of infants eligible to receive the covered benefit.

Cost-effectiveness studies conclude the following:

- Cost savings emerge particularly when using EHMD for VLBW infants with several risk factors for NEC, but not for all VLBW infants.<sup>108</sup>
- EHMDs for preterm infants under 750 grams at birth, and those who are at the highest risk of developing major complications, are likely to result in a \$107,567 cost savings per year. Providing EHMDs to higher weight class infants may be economically feasible depending on the pricing of the HMDF and the baseline risk of complications in the hospital setting.<sup>109</sup>
- EHMDs are both cost-saving and clinically beneficial for VLBW babies (<1,500 grams) in a U.S.-based setting, saving a reported \$117,239 per infant.<sup>110</sup>
- For VLBW infants in the NICU, the use of mother's milk supplemented with DHM provides positive cost return compared to mother's milk supplemented with formula.<sup>111</sup>
- Infants receiving a human milk diet with DHM-derived cream supplementation to address slow growth achieve appropriate growth in a cost-effective feeding strategy.<sup>112</sup>
- Newer bovine milk-derived fortifier (BMDF) may help in achieving optimal growth without increasing the risk of developing NEC and at a substantially lower cost compared to HMDF.<sup>113</sup>

While these cost savings are substantial, it remains unclear to what degree the proposed mandate will result in additional savings to insurance premiums. The limitations section of the Actuarial Assessment addresses this matter further.

### 3.0 Conclusion

The medical benefits are well established for use of human donor milk, instead of formula, for VLBW infants where mother's own milk is not available or sufficient. DHM for infants with VLBW clearly helps decrease the risk for NEC and may reduce risk of late-onset sepsis; chronic lung disease; ROP; and neurodevelopmental impairment.<sup>114</sup> When mother's own milk is unavailable or insufficient, DHM supplemented with a multi-nutrient fortifier is the first recommended alternative for infants with VLBW.<sup>115</sup>

VLBW infants often need additional fortifiers to supplement human milk to support their growth and neurodevelopment.<sup>116</sup> NICUs, as standard practice, use mother's or donor DHM with the addition of BMDF. The use of HMDF has been increasing, although remains limited due to substantial cost and a weak evidence basis for its comparative effectiveness over BMDF. Nonprofit milk banks provide DHM but do not provide fortifiers, which are sold separately by corporate distributors that market their own proprietary human-milk fortifiers. Overall, evidence supports the medical efficacy of fortifiers for preterm LBW infants. But evidence does not establish the comparative effectiveness of HMDF over BMDF when used with DHM.<sup>117</sup>

The medical efficacy findings generally pertain to a particular group of infants with specific medical need. The bill references such medical need by the infants in provisions iii(a) and iii(c), when mother's own milk is not available. However, the other independent eligibility criteria designated by iii(b); for infants with mothers "medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support" allows eligibility for infants under a much wider range of reasons. Evidence does not exist to support the

medical efficacy of DHM for the general population of otherwise healthy infants when the mothers are unable to lactate or unable to produce sufficient milk supply for their infants. In those cases, absent specific medical need by the infant, formula provides an acceptable alternative for feeding.<sup>118</sup>

The bills generally allow two groups of eligibility criteria:

- 1) Infants' medical necessity criteria
- 2) Mothers' eligibility criteria.

Table 2 displays the potential eligibility under the proposed bill as it relates to current practice and to existing evidence on medical efficacy.

- The yellow range includes eligibility criteria of 1, infant's medical necessity, along with 2, mother's eligibility criteria.
- The blue range includes eligibility criteria of 2 and may occur in the absence of criteria of 1.

**Table 2. Potential Eligibility, Current Practice, and Evidence for Use of DHM**

	Infants			
	<1,500 grams	<2,500 grams	Other applicable medical condition	Healthy infants
<i>Preterm, in-hospital, up to 34 weeks</i>	DHM with fortifiers: <ul style="list-style-type: none"> <li>• Medical efficacy established for DHM with fortifiers</li> <li>• DHM use consistent with current practice</li> <li>• Mixed evidence about comparative benefit of HMDF over BMDF</li> </ul>			N/A
<i>Infants up to 6 months of age</i>	DHM (no fortifiers): <ul style="list-style-type: none"> <li>• Medical efficacy not established, except for specific medical conditions for which formula is contraindicated.</li> <li>• Broader use of DHM may bring benefits similar to breastfeeding for all infants, but the use of DHM as a general substitute for breastfeeding is not current standard practice.(with exceptions for specific medical circumstances)</li> </ul>			

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## Appendix Table: State Medicaid and Commercial Insurance Coverage of DHM

Compiled from:

Rose, A.T., Miller, E.R., Butler, M. et al. US state policies for Medicaid coverage of donor human milk. *J Perinatol* 2022; 42, 829–834. Accessed September 8, 2022. <https://doi.org/10.1038/s41372-022-01375-9>.

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State/District	Medicaid	Commercial	Eligibility for coverage	Age limits	Inpatient	Home-based
California	Yes	■	Mother is unable to breastfeed due to medical reasons, and the infant cannot tolerate or has medical contra-indications to the use of any formula, including elemental formulas.	Silent	Yes	Yes
Connecticut	Yes	■	Documented medical necessity. (A) the infant is medically or physically unable to receive maternal breast milk or participate in breastfeeding, or (B) the infant's mother is medically or physically unable to produce maternal breast milk in sufficient quantities. State regulations establish infant birth weight and health conditions that may make the provision of pasteurized donor breast milk medically necessary and time limits for Medicaid coverage of pasteurized donor breast milk.	To be set by regulation	Silent	Silent
District of Columbia (Washington D.C.)	Yes	■	Infants unable to tolerate formula and documented medical necessity. 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 feeding trial every 180 days.	12 months	Yes	Yes
Illinois	Yes	Yes	Infant whose mother is medically or physically unable to produce maternal breast milk or produce it in sufficient quantities to meet the infant's needs, or the maternal breast milk is contraindicated; and donor human milk has been determined medically necessary for the infant and advantageous over commercially available formulas. Infants under age 6 months must have one of the following: 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 age, Medicaid will cover for recipient that have spinal muscular atrophy.	12 months; Medicaid may extend beyond	Yes	Yes
Kansas	Yes	■	Critically ill infant in NICU. DHM prescribed by an authorized individual. State determines medical necessity.	3 months	Yes	No
Kentucky	No	Yes	Prescribed for the prevention of NEC and associated comorbidities. Prescribed by a physician. Coverage is for 100% human milk diet with an inflation adjusted \$15,000 per plan year per infant.	Silent	Silent	Silent

State/District	Medicaid	Commercial	Eligibility for coverage	Age limits	Inpatient	Home-based
Louisiana	Yes	■	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.	12 months	Yes	No
Missouri	Yes	■	Critically ill infant in NICU. DHM prescribed by an authorized individual. State determines medical necessity. Milk bank meets state standards.	3 months	Yes	No
New Jersey	Yes	Yes	Medical necessity, under at least one of the following circumstances: (1) the infant is medically or physically unable to receive maternal breast milk or participate in breast feeding or the infant's mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breast feeding despite optimal lactation support; or (2) the infant meets any of the following conditions: a body weight below healthy levels, as determined by the licensed medical practitioner; a congenital or acquired condition that places the infant at a high risk for development of NEC; or a congenital or acquired condition that may benefit from the use of donor breast milk and human milk fortifiers as determined by the Department of Health.	6 months	Yes	Yes
New York	Yes	Yes	Medical necessity for infants who: 1) Have a documented birth weight of less than 1,500 grams; or 2) Have a congenital or acquired condition that places the infant at a high risk NEC and/or infection; or 3) Have other qualifying condition(s) as determined by the Commissioner of Health or his/her designee. Of infants meeting the designated medical conditions, coverage is for infants who are medically or physically unable to receive maternal breast milk or participate in breast feeding, or in cases where the mother is medically or physically unable to produce maternal breast milk at all or in sufficient quantities or is unable to participate in breast feeding despite optimal lactation support.	Silent	Yes	No
Ohio	Yes	■	Documented medical necessity.	Silent	Silent	Yes
Oregon	Yes	■	Must have all: 1) birth weight <1,500 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.	6 months	No	Yes
Pennsylvania	Yes	■	Medical necessity determined based American Academy of Pediatric clinical guidelines.	Silent	No	Yes

State/District	Medicaid	Commercial	Eligibility for coverage	Age limits	Inpatient	Home-based
Texas	Yes	■	Documented medical necessity. Inpatient coverage up to 6 months with medical necessity. Outpatient coverage up to 11 months. With inability to tolerate formula and medical necessity. Can be extended through 20 years of age.	6 months; 11 months.	Yes	Yes
Utah	Yes	■	DHM is medically necessary. Mother cannot provide milk.	11 months	No	Yes

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# AN ACT RELATIVE TO HUMAN DONOR MILK COVERAGE

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ACTUARIAL ASSESSMENT

## 1.0 Executive Summary

The Massachusetts Legislature's Committee on Health Care Financing referred House Bill (H.B.) 1106 and Senate Bill (S.B.) 717, both titled "An Act Relative to Human Donor Milk Coverage<sup>1</sup>—to the Massachusetts Center for Health Information and Analysis (CHIA) for review. The bill requires health insurers to cover pasteurized donated human breast milk, including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health, Massachusetts General Law (MGL).

Chapter 3 §38C requires CHIA to review the medical efficacy of treatments or services included in each mandated benefit bill referred to the agency by a legislative committee should it become law. CHIA must also estimate each bill's fiscal impact, including changes to premiums and administrative expenses. This report provides the fiscal analysis.

This report references H.B.1106 and S.B. 717 together and hereafter as "the bills."

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for the purposes of Commonwealth of Massachusetts (Commonwealth) defrayal under the Affordable Care Act (ACA), nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance mandate requiring Commonwealth defrayal.

### 1.1 Current Insurance Coverage

BerryDunn surveyed 10 insurance carriers in the Commonwealth, and six responded. None of these carriers currently offer coverage of Donor Human Milk (DHM) in their commercial insurance plans. One plan noted that it would only consider coverage for MassHealth (Medicaid) currently under the federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirement(s). If such coverage were needed, this plan noted that it would look to the American Academy of Pediatrics (AAP) policy on the use of DHM as a guide.

### 1.2 Analysis

The bill requires health insurance carriers that provide medical expense coverage for pasteurized donated human breast milk (DHM), including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health.

### 1.3 Summary Results

The estimated impact of the proposed requirement on medical expense and premiums appears below. The analysis includes development of a best estimate mid-level scenario, along with a low-level scenario, and a high-level scenario using more conservative assumptions. The impact on premiums is driven by the provisions that carriers cover DHM and human-milk-derived fortifiers (HMDF), and these costs are offset by the reduction in costs in use of enteral formulas. Variation between scenarios is attributable to the uncertainty surrounding the number of infants potentially receiving the covered benefit and length of time that each infant will require DHM and HMDF.

A relatively small number of in-hospital very low birthweight (VLBW, weight below 1,500 grams) and low birthweight (LBW, weight below 2,500 grams) infants are born annually and require DHM and HDMF for relatively short time periods, thereby rendering only a small impact on premiums by this segment of the target population. The covered benefit for medically needy in-hospital infants accounts for only 2% of the bill's estimated marginal premium cost in the mid-scenario.

However, other infants eligible for the covered benefit—those with mothers “medically or physically unable to produce maternal breast milk in sufficient quantities”—account for approximately 98% of the claims cost in the mid-scenario. The provision of the bill extends coverage to out-of-hospital infants, through age six months, based on a potentially wide range of maternal factors. Through this mechanism, insurance may fund DHM as a substitute for formula for a potentially large number of healthy infants.

Table ES-1 displays the impact on first-year (2023) claims by each of the component parts of the bill, and Table ES-2 displays the summary results for a five-year period. This analysis estimates that the bill, if enacted as drafted for the General Court, would increase fully insured premiums by as much as 0.976% on average over the next five years; a more likely increase is approximately 0.731%, equivalent to an average annual expenditure of \$116.5 million over the 2023 – 2027 period. The impact on premiums is driven largely by the provision of DHM coverage for infants through age 6 months based on maternal criteria rather than infant medical necessity.

**Table ES-1. Projected PMPM Claims Cost, 2023**

	LOW	MID	HIGH
Donor Human Milk – LBW and NEC infants	\$0.01	\$0.02	\$0.03
Human Milk-Derived Fortifier for LBW infants	\$0.04	\$0.05	\$0.07
Donor Human Milk –months 1-6 based on maternal criteria	\$2.33	\$3.50	\$4.67
Offset – Reduction in payments for enteral formula	<\$0.01>	<\$0.01>	<\$0.01>
<b>Total</b>	<b>\$2.37</b>	<b>\$3.57</b>	<b>\$4.76</b>

**Table ES-2. Summary Results**

	2023	2024	2025	2026	2027	WEIGHTED AVERAGE	FIVE- YEAR TOTAL
Average Members (000s)	2,156	2,242	2,262	2,266	2,269		
Medical Expense Low (\$000s)	\$44,224	\$65,050	\$66,946	\$68,381	\$69,834	\$66,458	\$314,435
Medical Expense Mid (\$000s)	\$66,528	\$97,863	\$100,721	\$102,886	\$105,078	\$99,987	\$473,076
Medical Expense High (\$000s)	\$88,832	\$130,677	\$134,496	\$137,391	\$140,323	\$133,517	\$631,718
Premium Low (\$000s)	\$51,508	\$75,764	\$77,972	\$79,643	\$81,336	\$77,403	\$366,223
Premium Mid (\$000s)	\$77,485	\$113,982	\$117,310	\$119,831	\$122,385	\$116,455	\$550,993
Premium High (\$000s)	\$103,463	\$152,199	\$156,647	\$160,019	\$163,434	\$155,508	\$735,763
PMPM Low	\$2.76	\$2.82	\$2.87	\$2.93	\$2.99	\$2.88	\$2.88
PMPM Mid	\$4.15	\$4.24	\$4.32	\$4.41	\$4.49	\$4.33	\$4.33
PMPM High	\$5.55	\$5.66	\$5.77	\$5.89	\$6.00	\$5.79	\$5.79
Estimated Monthly Premium	\$562	\$577	\$593	\$609	\$625	\$593	\$593
Premium % Rise Low	0.491%	0.488%	0.484%	0.481%	0.478%	0.486%	0.486%
Premium % Rise Mid	0.739%	0.734%	0.729%	0.724%	0.719%	0.731%	0.731%
Premium % Rise High	0.987%	0.980%	0.973%	0.966%	0.960%	0.976%	0.976%

Note: Figures in Table ES-2 differ from Table ES-1 because ES-1 reflects dollars based on a membership snapshot used in the development of the PMPMs. Table ES-2 displays projected membership based on a population projection. Table ES-2 summary table also applies a 72% adjustment factor to the first year (2023) of implementation to account for ramp up in implementation.



## 2.0 Introduction

As submitted to the 192<sup>nd</sup> General Court of the Commonwealth of Massachusetts, H.B. 1106 and S.B. 717 (“the bills”) require health insurers to cover pasteurized donated human breast milk (DHM), including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health.

The bill specifies the eligibility for coverage of DHM for infants that meet criteria summarized in Items 1, 2, and 3, below:

1. The covered person is an infant under the age of six months; **and**
2. The milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health; **and**
3. A licensed medical practitioner has issued a written order for the provision of such human breast milk for an infant who meets any of Items in 3a, 3b, or 3c below:
  - a) Is medically or physically unable to receive maternal breast milk or participate in breastfeeding; **or**
  - b) Whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support; **or**
  - c) Meets any of the following conditions:
    - i. A body weight below healthy levels determined by the licensed medical practitioner; **and/or**
    - ii. A congenital or acquired condition that places the infant at a high risk for development of necrotizing enterocolitis; **and/or**
    - iii. A congenital or acquired condition that may benefit from the use of such human breast milk as determined by the Department of Health.

Section 3.0 of this analysis outlines the provisions and interpretations of the bill. Section 4.0 summarizes the methodology used for the estimate. Section 5.0 discusses important considerations in translating the bills’ language into estimates of its incremental impact on healthcare costs and steps through the calculations. Section 6.0 discusses results.

## 3.0 Interpretation of the Bill

### 3.1 Reimbursement for Donor Human Milk

The bills require health insurers to cover DHM, including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health.

### 3.2 Plans Affected by the Proposed Mandate

The bill amends statutes that regulate commercial healthcare carriers in the Commonwealth. It includes the following sections, each of which addresses statutes dealing with a particular type of health insurance policy when issued or renewed in the Commonwealth:<sup>2</sup>

- Chapter 32A – Plans Operated by the Group Insurance Commission (GIC) for the Benefit of Public Employees
- Chapter 175 – Commercial Health Insurance Companies
- Chapter 176A – Hospital Service Corporations
- Chapter 176B – Medical Service Corporations
- Chapter 176G – Health Maintenance Organizations (HMOs)

Self-insured plans, except for those managed by the Group Insurance Commission (GIC), are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, the benefits of which are qualified by Medicare. This analysis excludes members over 64 years of age who have fully insured commercial plans, and this analysis does not address any potential effect on Medicare supplement plans, even to the extent they are regulated by state law. Although the bill includes Chapter 118, this analysis does not estimate the bill's impact to MassHealth.

### 3.3 Covered Services

BerryDunn surveyed 10 insurance carriers in the Commonwealth, and 6 responded. None of these carriers currently offer coverage of DHM in their commercial insurance plans. One plan noted that it would only consider coverage for MassHealth (Medicaid) currently under the federal EPSDT requirement(s). If such coverage were needed, this plan noted that it would look to the American Academy of Pediatrics (AAP) policy on the use of HDM as a guide.

### 3.4 Existing Laws Affecting the Cost of the Bill

MGL c.175 § 47I, "Nonprescription enteral formulas for home use," mandates coverage of nonprescription enteral formulas for home use when deemed medically necessary for the treatment of malabsorption due to Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids.<sup>3</sup> Additionally, this statute requires coverage of up to \$5,000 annually per insured individual for food products that have been modified to be "low protein" for those with inherited disease(s) of amino acids and organic acids. With this prior mandate, this current assessment of the bills includes an offset to account for reduction in enteral formula expenses (Section IV. E.4).

## 4.0 Methodology

### 4.1 Overview

As submitted to the 192<sup>nd</sup> General Court of the Commonwealth of Massachusetts, the bill requires health insurance carriers to cover pasteurized donated human breast milk, including human milk fortifiers, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health.

The incremental cost of coverage for DHM is estimated using claims data from the Massachusetts All-Payer Claims Database (APCD), along with data from the Massachusetts Registry of Vital Records and Statistics (RVRS), to determine the number of eligible infants. Published literature and interviews with Massachusetts clinical experts are used to determine the cost of DHM and HDMF, and the timing and frequency and amount for provision of DHM and HDMF to infants. The number of infants is multiplied by the cost per infant and frequency to determine the incremental claims amounts. Adding carrier retention to the incremental claims amounts results in a baseline estimate of the proposed mandate's incremental effect on premiums, which is projected over the five years following the assumed January 1, 2023, implementation date of the proposed law.

### 4.2 Data Sources

The primary data sources used in the analysis are as follows:

- Input from legislative sponsors, providing information about the intended effect of the bill
- Survey of commercial carriers in the Commonwealth, gathering descriptions of current coverage
- Interviews with the following:
  - Dr. Margaret Parker, MD, MPH, a neonatologist at the University of Massachusetts Memorial Medical Center in Worcester and the lead author of the recent American Academy of Pediatrics statement on human milk for VLBW infants. She has a scholarly research background related to breastfeeding and human milk, including DHM, with dozens of papers published in peer-reviewed journals.
  - Dr. Sarah Taylor, a neonatologist at Yale University School of Medicine, a Professor of Pediatrics (Neonatal-Perinatal Medicine) and Director of Clinical Research, Pediatrics, and a recognized authority on breastfeeding and use of DHM.
  - Deborah Youngblood, PhD, Executive Director, Mothers' Milk Bank Northeast, a member of Human Milk Banking Association of North America (HMBANA), located in Newton, Massachusetts.
- Massachusetts All-Payer Claims Database (APCD)
- Published scholarly literature, reports, and population data, cited as appropriate

## 4.3 Steps in the Analysis

This section summarizes the analytic steps used to estimate the impact of the bill on premiums.

### 1. Estimated the marginal costs to insurers for DHM for infants meeting medical necessity criteria.

The process to estimate the cost of DHM-use based on infant medical necessity involved the following steps:

- A. Used information gathered in expert interviews to determine the cost per ounce of DHM
- B. Used publicly available literature and information gathered in expert interviews to determine the number of ounces per day needed on average for each infant
- C. Multiplied the cost per ounce from Step A by the number of ounces from Step B to calculate the cost per day
- D. Used publicly available literature and information gathered in expert interviews to determine the number of days that DHM is needed
- E. Multiplied the cost per day from Step C by the average number of days in Step D to calculate the cost per infant
- F. Used the APCD, publicly available literature, and information gathered in expert interviews to estimate the number of infants needing DHM
- G. Multiplied the cost per infant from Step E by the number of infants to determine the incremental cost
- H. Divided the incremental cost from Step G by the corresponding member months to calculate the incremental per-member per-month (PMPM) cost

### 2. Estimated the cost of human-milk-derived fortifiers (HMDF)

The process to estimate the cost of fortifiers involved the following steps:

- A. Used publicly available literature and information gathered in expert interviews to determine the cost per day for HMDF
- B. Used publicly available literature and information gathered in expert interviews to determine the number of days that HMDF is needed
- C. Multiplied the cost per day from Step A by the average number of days from Step B to calculate the cost per infant
- D. Used the APCD, publicly available literature, and information gathered in expert interviews to estimate the number of infants needing HMDF
- E. Multiplied the cost per infant from Step C by the number of infants from Step D to determine the incremental cost
- F. Divided the incremental cost from Step E by the corresponding member months to calculate the incremental PMPM cost

### 3. Estimated the marginal costs to insurers for DHM for infants based on mothers' eligibility criteria

The process to estimate the cost of DHM for infants based on mothers' eligibility criteria involved the following steps:

- A. Used publicly available literature and information gathered in expert interviews to determine the cost per ounce of DHM
  - B. Used publicly available literature and information gathered in expert interviews to determine the number of ounces per day need on average for each infant
  - C. Multiplied the cost per ounce in Step A by the number of ounces in Step B and by 30.1 days in a month to calculate the cost per month
  - D. Used publicly available data about current breastfeeding rates of Massachusetts mothers for infants at birth, at eight weeks, and at six months, to estimate the number of mothers potentially seeking use of DHM in place of formula
  - E. Used guideline in the bill (provision of covered benefit up to six months), along with data about number of Massachusetts mothers currently not breastfeeding at infant through 6 months, to estimate the average number of infant months that DHM may be used for infants not in the hospital
  - F. Multiplied the non-breastfed infant months by an estimated DHM take-up rate to estimate the annual DHM infant months
  - G. Multiplied the annual DHM infant months from Step F by the cost per month from Step C to calculate the incremental claims cost
  - H. Divided the incremental cost from Step F by the corresponding member months to calculate the incremental PMPM cost
4. **Calculated the potential cost offset of existing coverage of enteral formulas and its impact on the total marginal cost estimate**
- A. Used claims data from the APCD to determine the total cost for enteral formulas
  - B. Divided the total claims cost for enteral formulas in Step A by the total commercial fully insured members to calculate PMPM cost for existing coverage
  - C. Projected PMPM claims cost over the analysis period using an estimated increase in professional services
5. **Calculated the impact of the projected claim costs on insurance premiums.**
- A. Added the incremental cost from calculated in Steps 1, 2, and 3 and subtracted the offset from Step 4 to calculate the total incremental claims impact
  - B. Estimated the fully insured Commonwealth population under age 65, projected for the next five years (2023 – 2027)
  - C. Multiplied the PMPM incremental net cost of the mandate by the projected population estimate, to calculate the total estimated marginal claims cost of the bill

- D. Estimated insurer retention (administrative costs, taxes, and profit) and applied the estimate to the final incremental claims cost calculated in Step C

#### 4.4 Assumptions and Limitations

Carriers in Massachusetts reported that they do not currently provide coverage for DHM and HMDF, so the marginal cost of the bill is due to the requirement of adding this coverage. These estimates involve several assumptions, uncertainties, and limitations:

##### ***Length of time eligible infants will require and use DHM:***

The bill specifies that infants may be eligible for the covered benefit up to six months of age. However, the analysis requires an estimate of how long infants are likely to receive DHM, either as a supplement or replacement to mother's own milk or infant formula. This length of time will vary depending on the medical need of the infant and on other circumstances that affect the mother's ability to lactate sufficiently during the six-month period. BerryDunn's analysis uses two approaches: for infants in NICU, BerryDunn uses an estimated average number of days based on data about preterm infant length of stay. For infants not in the hospital, BerryDunn estimates the average number of days for provision of DHM, based on data about Massachusetts' mothers' rates of breastfeeding at infant birth and at six months.

In addition, human milk fortifiers are typically used only until infants reach about 34 weeks adjusted gestational age or 2,000 grams weight.<sup>4</sup> The total number of days or weeks required for use depends on 1) the number of infants born at various weeks of gestation and 2) how much those infants rely on DHM relative to receiving mother's own milk. The BerryDunn analysis provides lower-, middle-, and upper-bound estimates for the length of provision of the DHM and for the average length of provision of the fortifier.

##### ***Total number of infants eligible to receive the covered benefit:***

The State of New Jersey has a coverage mandate with language identical to that proposed for Massachusetts and New Jersey's experience provides perspective on the challenges in estimating the fiscal impact of Massachusetts' proposed mandate.<sup>5</sup> The New Jersey Legislature's fiscal estimate for the bill reports that "cost to provide these services cannot be quantified with any certainty as ... the number of individuals who will receive these services is unpredictable."

This analysis for Massachusetts requires an estimate of the number of in-hospital (NICU) infants who would require nutrition other than mother's own milk. Most NICU mothers of very preterm infants may be unable to provide all the milk necessary for their preterm infants.<sup>6</sup> To estimate the potentially eligible population of infants with medical need, the BerryDunn analysis uses Massachusetts' total number of LBW infants and the number of infants with NEC.

The proposed bill also allows coverage of DHM for infants with mothers "medically or physically unable to produce maternal breast milk in sufficient quantities." There are many reasons (discussed in the Medical Necessity section of this report) that a mother may be unable to produce sufficient quantities of breastmilk for their infant up to age six months.<sup>7</sup> Under this component of the proposed bill, the number of mothers who will seek access to DHM is

uncertain. With insurance coverage available, some mothers who currently use formula may choose to switch to DHM, while others may continue using formula. The more detailed, step-by-step description of the estimation process in the next sections addresses these uncertainties further.

***The total amount of DHM needed:***

The uncertainty about the number of infants eligible also brings uncertainty about the total volume of DHM this new insurance benefit would confer. For in-hospital infants, a study quantifying the cost of using DHM in the NICU suggests there are four categories of DHM need/use:<sup>8</sup> 1) minimal DHM supplement for infants of mothers who provide sufficient breast milk; 2) moderate use of DHM to supplement for infants of mothers who produce insufficient milk supply during hospital stay; 3) greater DHM use for infants who receive some mother's own milk during hospital stay, but who go home on formula; and 4) highest DHM use for infants who receive no mother's own milk during hospital stay. Each level of use brings different costs. The BerryDunn analysis does not provide this level of granularity for the hospital-based infant population, given the relatively small total number of infants affected.

To estimate potential use of DHM out-of-hospital (home use), BerryDunn consulted multiple sources that reported estimates ranging from 8 ounces to up to 48 ounces per day for infants up to six months of age.<sup>9</sup> New Jersey's Office of Legislature, in its fiscal estimate for a DHM insurance coverage, estimates that infants between 1 and 6 months of age need approximately 25 ounces of milk daily. Using low- and high-range pricing examples for DHM, this resulted in an estimated cost of between \$1,500 and \$3,375 to provide 25 ounces of DHM milk per month to a qualifying infant under the New Jersey bill.<sup>10</sup>

BerryDunn used an estimate of an average of 10 ounces per day for medically needy infants in-hospital receiving DHM, recognizing that these LBW infants consume smaller quantities. For analysis of out-of-hospital infants ages up to six months, BerryDunn's analysis here uses an estimation of a range of between 20 and 40 ounces per day for healthy infants receiving DHM.

This part of the BerryDunn analysis also relies on currently reported rates of breastfeeding by Massachusetts mothers at infants' birth, three months, and six months of age. Among those infants not breastfed (currently receiving formula), this analysis applies a multiplier to estimate what portion would convert to use of DHM in place of formula. However, this study does not have clear data on the specific levels of breastfeeding at birth, three, and six months (beyond "exclusive" or "not exclusive") so cannot account for how much DHM might be used as a supplement to breast milk for those infants who are breastfed through age six months.

Also, the bill language includes, as eligible for the covered benefit, infants "whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support." (Emphasis added). The clause "or participate in breastfeeding" is sufficiently broad, such that some mothers who currently provide their own milk to their infants through age six months (perhaps pumping milk at work or reducing their employment) may find it more attractive to use the new insurance benefit to switch to DHM. The potential change from mother's own milk to DHM is possible, but not factored into this analysis.

***Supply of DHM:***

This analysis does not factor in potential constraints on the supply of DHM should the use of and demand for the product increase substantially. Currently, nonprofit milk banks provide most DHM to infants in hospitals, with very limited supply available for infants in the community.<sup>11</sup> These nonprofit milk banks do not pay their donors, and have limited supply available, generally for specific infants with a designated medical need.

Commercial products are available from suppliers that pay women for the provision of their milk, and sell the product, at a price substantially higher than nonprofit milk bank prices.<sup>12</sup> This supply may be more flexible and potentially capable of increasing to meet expanded demand (although ethical concerns have been noted about this potential practice).<sup>13,14</sup> The current analysis does not factor in any potential constraints on supply, but does apply differing prices. BerryDunn applies the price for the nonprofit milk bank product to the population of in-hospital infants with medical needs, and applies the commercial sector price for infants ages birth to 6 months qualifying under the mothers' eligibility criteria.

***Potential reduction in claims cost due to health benefits of DHM:***

It remains unclear to what degree the proposed mandate will result in additional savings to claims costs due to health benefits of DHM. That will depend on the degree to which infants are not receiving DHM today that would receive it under the mandate. A 2020 paper reports the routine use of DHM in 88% of Level 3 and 4 NICUs (responding to a survey).<sup>15</sup> Interviews with leading neonatologists suggest that current standard practice includes provision of DHM to infants in NICUs, with hospitals currently incurring the cost themselves.<sup>16</sup> In that case, insurance premiums already reflect the savings that result from the provision of the DHM to these infants. The bills would not change current practice but, rather, shift the expense from hospitals to insurance carriers. In that case, the change may not result in additional savings to the insurance carrier.

The State of New Jersey has a coverage mandate with language identical to that proposed for Massachusetts.<sup>17</sup> New Jersey's fiscal estimate notes that expenditures on this mandate may result in a decrease in medical costs associated with the care of infants, but that such savings cannot be quantified with certainty such that they may be attributed to the provisions of the bill.<sup>18</sup>

As noted, hospitals much less frequently use HMDF, and the bills are likely to increase the use of this fortifier. However, the cost impacts reported in the literature are not clearly due to the use of such fortifier, apart from DHM itself (as discussed in the Medical Efficacy section of this report). For this reason, the actuarial analysis assesses only the direct effect of the mandate on health insurance premiums and does not factor in any potential savings associated with broader adoption of HMDF.

***Effect of COVID-19 on the insured population numbers:***

Another other important limitation to this analysis: COVID-19 has impacted the number of commercial fully insured members in 2020 through 2022. Fully insured membership declined due to decreased enrollment in employer-sponsored insurance (ESI). The impact that COVID-19 and economic trends will have on employment and, therefore, ESI in the 2023 – 2027 projection period is uncertain. Appendix A further addresses the limitations related COVID-19.



## 5.0 Analysis

This section describes the calculations outlined in the previous section in more detail. The analysis includes a best estimate middle-cost scenario, along with a low-cost scenario, and a high-cost scenario using more conservative assumptions. The analysis section proceeds as follows:

- Section 5.1 describes the steps used to calculate the PMPM expenses associated with infants needing DHM based on medical necessity.
- Section 5.2 describes the steps used to calculate the PMPM expenses associated with infants needing HMDF.
- Section 5.3 describes the steps used to calculate the PMPM expenses associated with infants needing DHM based on the maternal population.
- Section 5.4 describes the steps used to calculate the PMPM cost offset due to eliminating enteral formula expenses.
- Section 5.5 aggregates the marginal PMPM costs.
- Section 5.6 projects the fully insured population age 0 to 64 in the Commonwealth over the years 2023 to 2027 analysis period.
- Section 5.7 calculates the total estimated marginal cost of the bill.
- Section 5.8 adjusts these projections for carrier retention to arrive at an estimate of the bill's effect on premiums for fully insured plans.

It is important to note that the cost estimates for the relatively small number of infants in the NICU after birth have greater precision, as clear medical necessity and intensive in-hospital and post-discharge care processes define a relatively clear rate of use of HDM (and HMDF). The HDM estimates for the much larger number of relatively healthy out-of-hospital infants, through age six months, are much more uncertain, with very low current use of HDM in this population and the difficult-to-predict effects of various coverage provisions under the proposed bill. Relevant factors that lack clarity include “medically or physically unable to participate in breastfeeding,” the inclination of mothers to seek a written order from a licensed medical practitioner, and the way practitioners would interpret the criteria in making approval decisions. These uncertainties result in a relatively wide range of estimates for potential DHM take-up/use by non-hospital infants through six months of age.

### 5.1 Coverage for DHM for Infants in Need Based on Medical Necessity

The proposed legislation requires insurers to cover DHM, including HMDF, if ordered by a licensed medical provider for an infant under the age of six months, and the milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health. Carriers in Massachusetts do not cover DHM or HMDF. In this section, BerryDunn calculates the incremental cost component associated with infants needing DHM based on medical necessity of the infant.

This section requires estimates of the following:

- Cost per ounce and per day of DHM
- Number of ounces per day per infant
- Number of days consuming DHM
- Number of infants that will receive the covered benefit
- Total cost and PMPM cost

### ***Cost per Ounce and Ounces per Day***

The range in cost for DHM is \$3 to \$5, plus shipping fees, compared to the range in cost for formula of \$0.50 to \$1 per ounce under normal supply conditions.<sup>19</sup> The Mothers' Milk Bank Northeast, which supplies DHM for Massachusetts (among other states/regions), reports current pricing as of September 2022 at approximately \$4.18 per ounce for its most commonly distributed units.<sup>20</sup>

BerryDunn consulted multiple sources reporting estimates ranging from 8 to 30 ounces per day for infants up to 6 months of age.<sup>21</sup> BerryDunn used an estimate of an average of 10 ounces per day for VLBW or LBW infants receiving DHM, recognizing that premature infants will be on the lower end of consumption estimates. BerryDunn multiplied the number of ounces by the cost per ounce to calculate the cost per infant per day. Table 1 displays the results.

**Table 1. DHM Cost Per Infant Per Day**

	<b>COST PER OUNCE</b>	<b>NUMBER OF OUNCES</b>	<b>COST PER DAY</b>
	\$4.18	10	\$41.76

BerryDunn multiplied the cost per day in Table 1 by the 2.0% annual increase in the Consumer Price Index (CPI)<sup>22</sup> for food, to estimate the PMPM cost of DHM over the projection period. Table 2 displays these results.

**Table 2. Projected Cost Per Infant Per Day**

	<b>2022</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>
	\$41.76	\$42.60	\$43.45	\$44.32	\$45.21	\$46.11

### ***Number of Days Consuming DHM***

The bills specify that infants may be eligible for the covered benefit up to six months of age. However, the analysis requires an estimate of how long infants are likely to receive DHM, either as a supplement or replacement to mother's own milk or infant formula. This length of time will vary depending on the medical need of the infant, and on other circumstances that affect the mother's ability to lactate sufficiently during the six-month period. The BerryDunn

analysis uses two approaches: For infants in NICU, BerryDunn uses an estimated average number of days based on data about preterm infant length of stay. For infants not in the hospital, BerryDunn estimates the average number of days for provision of DHM, based on data about Massachusetts' mothers' rates of breastfeeding at infant birth and at six months.

The total cost per infant depends upon the number of days each infant receives DHM. Infants in the hospital typically receive DHM until they reach about 34 weeks adjusted gestational age or 2,000 grams weight.<sup>23</sup> The total number of days or weeks required for use depends on the number of infants born at various weeks gestation, and how much those infants rely on DHM relative to receiving mother's own milk. The BerryDunn analysis provides lower, middle, and upper bound estimates for length of provision of the DHM, starting with estimates of between 4 and 10 weeks or between 28 and 70 days. BerryDunn adjusted the number of days assuming that insurance coverage would result in a modest increase in the average number of days infants receive DHM. BerryDunn assumed in the low scenario that infants would receive DHM for 30 days, for 60 days in the mid-scenario, and for 90 days in the high scenario. BerryDunn multiplied the cost per infant per day by the number of days to get the total cost per infant. Table 3 displays these results.

**Table 3. Projected Cost Per Infant**

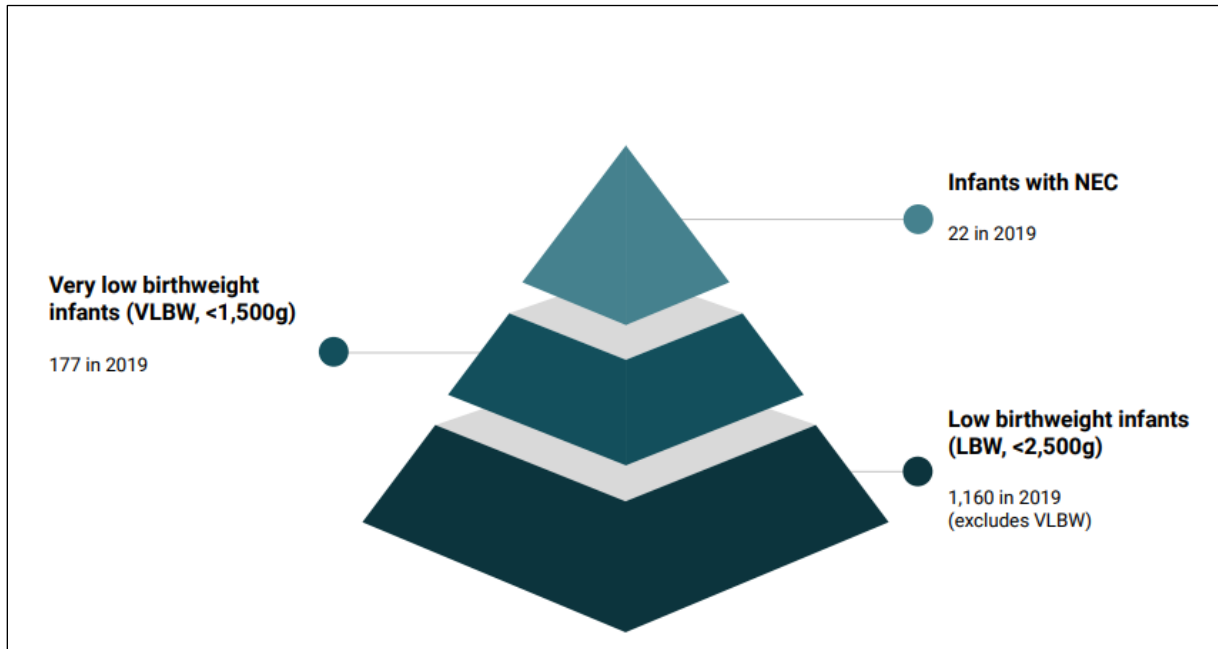
	2022	2023	2024	2025	2026	2027
Low Scenario	\$1,253	\$1,278	\$1,304	\$1,330	\$1,356	\$1,383
Mid-Scenario	\$2,506	\$2,556	\$2,607	\$2,659	\$2,712	\$2,767
High Scenario	\$3,759	\$3,834	\$3,911	\$3,989	\$4,069	\$4,150

### ***Number of Infants Who Will Receive the Covered Benefit***

This analysis requires an estimate of the number of in-hospital (NICU) infants who would require nutrition other than mother's own milk. Most NICU mothers of very preterm infants may be unable to provide all milk necessary for their preterm infants.<sup>24</sup> To estimate the potentially eligible population of infants with medical need, the BerryDunn analysis uses Massachusetts' total number of LBW infants and the number of infants with NEC.

Based on the APCD, there were 1,337 infants with LBW and VLBW (1,160 infants LBW infants, excluding VLBW, and 177 VLBW infants) in 2019. There were an additional 22 infants with NEC, and the total was 1,359. These infants make up the DHM-eligible population. Figure 1 displays this population.

**Figure 1. Commercial Fully Insured Infants in Massachusetts with Medical Necessity for DHM\***



*\*Other infants with specific medical conditions will also qualify on a case-by-case basis, including after gut surgery, after cardiac surgery or with other rare and severe feeding intolerance.<sup>25</sup>*

### Total Cost and PMPM

Massachusetts-specific data are available from the CDC Breastfeeding Report Cards<sup>26</sup> and National Immunization Survey (NIS) data.<sup>27,28</sup> BerryDunn estimates, with these sources, that approximately 16% of mothers of LBW/VLBW infants will not provide breastmilk for their infants. BerryDunn multiplied 1,359 LBW/VLBW/NEC infants by this 16% to estimate that 217 infants would receive DHM. BerryDunn multiplied the cost per infant from Table 3 by 217 infants to calculate the incremental claims cost. Table 4 displays these results.

**Table 4. Projected Total Cost DHM for Medically Needy Infant Population**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$272,440	\$277,888	\$283,446	\$289,115	\$294,897	\$300,795
Mid-Scenario	\$544,879	\$555,777	\$566,892	\$578,230	\$589,795	\$601,591
High Scenario	\$817,319	\$833,665	\$850,338	\$867,345	\$884,692	\$902,386

BerryDunn next divided the incremental claims cost from Table 4 by the corresponding member months to calculate the PMPM cost shown in Table 5.

**Table 5. Projected PMPM Cost DHM for Medically Needy Infant Population**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
Mid-Scenario	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02
High Scenario	\$0.03	\$0.03	\$0.03	\$0.03	\$0.04	\$0.04

## 5.2 Coverage for HMDF Human-Milk-Derived Fortifiers (HMDF)

In this section, BerryDunn calculates the incremental cost component associated with infants needing HMDF.

This analysis requires estimates of the following:

- Cost per infant per day of HMDF
- Length of time (number of days) infants are receiving HMDF
- Number of infants receiving HMDF
- Total cost and PMPM

### Cost per Infant per Day for HMDF

Prolacta's fortifiers start at approximately \$180 an ounce; with a premature infant consuming about \$100 to \$300 worth of fortifier a day.<sup>29</sup> In 2015, the *New York Times* reported that human milk would typically cost \$10,000 over several weeks.<sup>30</sup> Based on literature, this analysis uses an average cost per day for HMDF of \$150.00.<sup>31</sup> BerryDunn multiplied the cost per day by the 2% annual increase in the Consumer Price Index (CPI)<sup>32</sup> for food to estimate the PMPM cost of HMDF over the projection period. Table 6 displays these results.

**Table 6. Projected HMDF Cost Per Infant Per Day**

	2022	2023	2024	2025	2026	2027
Cost per infant per day	\$150.00	\$153.00	\$156.06	\$159.18	\$162.36	\$165.61

### Number of Days Receiving HMDF

The bill specifies that infants may be eligible for the covered benefit for up to six months of age. However, the analysis requires an estimate of how long infants are likely to receive fortifiers. HMDFs are typically used only until infants reach about 34 weeks adjusted gestational age or 2,000 grams weight.<sup>33</sup> The total number of days or weeks required for use depends on the number of infants born at various weeks gestation, and 2) how much those infants rely on DHM relative to receiving mother's own milk. The BerryDunn analysis provides lower-, middle-, and upper-bound estimates for length of provision of fortifier.

BerryDunn assumed in the low scenario that infants would receive HMDF for 30 days, for 45 days in the mid-scenario, and for 60 days in the high scenario. BerryDunn multiplied the cost per infant per day by the number of days to obtain the total cost per infant. Table 7 displays the results.

**Table 7. Projected HMDF Cost Per Infant**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$4,500	\$4,590	\$4,682	\$4,775	\$4,871	\$4,968
Mid-Scenario	\$6,750	\$6,885	\$7,023	\$7,163	\$7,306	\$7,453
High Scenario	\$9,000	\$9,180	\$9,364	\$9,551	\$9,742	\$9,937

### Number of infants Receiving HMDF

Based on the APCD, there were 177 infants with VLBW in 2022. There were an additional 22 infants with NEC for a total of 199 infants. These infants make up the HMDF eligible population. According to the Massachusetts neonatologists, all of these infants would receive HMDF.

### Total Cost and PMPM

BerryDunn multiplied the cost per infant from Table 8 by the 199 infants to calculate the incremental claims cost. Table 8 displays the results.

**Table 8. Projected Cost HMDF**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$895,500	\$913,410	\$931,678	\$950,312	\$969,318	\$988,704
Mid-Scenario	\$1,343,250	\$1,370,115	\$1,397,517	\$1,425,468	\$1,453,977	\$1,483,057
High Scenario	\$1,791,000	\$1,826,820	\$1,863,356	\$1,900,624	\$1,938,636	\$1,977,409

Then BerryDunn divided the incremental claims cost from Table 8 by the corresponding member months to calculate the PMPM cost shown in Table 9.

**Table 9. Projected PMPM Cost of HMDF**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04
Mid-Scenario	\$0.05	\$0.05	\$0.06	\$0.06	\$0.06	\$0.06
High Scenario	\$0.07	\$0.07	\$0.07	\$0.08	\$0.08	\$0.08

### 5.3 Coverage for DHM for Infants Eligible by Maternal Factors

The bill, under provision 3a allows eligibility for infants “whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding despite optimal lactation support.” This component of the bill does not require a need by the infant and may extend this covered benefit to otherwise healthy babies whose families believe they are better off consuming human milk than formula. Section 2.1 in the Efficacy Review report reviews the potential wide range of reasons that mothers may be unable to sufficiently to meet their babies’ needs.

In this section, BerryDunn calculates the incremental cost component associated with the infants needing DHM based on infants with mothers “medically or physically unable to produce maternal breast milk in sufficient quantities.”

This analysis requires the following estimates:

- Number of infants and infant months not receiving breast milk at infant ages up to 6 months
- Average monthly cost of DHM per infant per month
- Expected rate of take-up (use of DHM) by the potentially eligible maternal-infant population

- Total cost and PMPM

The introduction to Section 5 notes the challenges in estimating the number of infants with mothers who may be “medically or physically unable” to breastfeed, and the number of days/months the DHM benefit would be used by these infants. The following analysis starts with available valid data about the proportion of mothers who do not breastfeed during each month after birth through infant age six months, and then applies those data to a potential take-up rate for DHM. It is uncertain how the take-up rate might vary, along with the number of ounces per day required by infants. A wide range of variations and combinations may occur in both the take-up rate and the ounces per day, producing multiple and widely varying DHM use and cost estimates. These numbers will depend on the interpretation of the bill language by mothers, medical practitioners, and insurance carriers, and also the interest by mothers in substituting DHM where they would otherwise have used a commercial infant formula. The analysis presented here displays findings for variation in number ounces per day at a single mid-range take-up rate.

### ***Average Number of Days the Potentially Eligible Infant Population May Receive DHM***

The length of time that women did not breastfeed varies. CDC-reported pregnancy survey data for Massachusetts reports that 9% of women never breastfeed.<sup>34</sup> Their infants could, in the proposed bill, receive DHM up to 6 months of age. CDC data indicate that, by 6 months, approximately 37% of Massachusetts infants are not breastfeeding.

BerryDunn used the following steps to estimate the average length of time that infants in the fully insured population may rely on DHM:

- a. Total number of infants potentially receiving the covered benefit: The Massachusetts Department of Public Health reported 41,981 births for the commercially insured population in 2019.<sup>35</sup> Of the commercial population, 42.0% of covered members were fully insured. (See Appendix A for discussion of excluding those members in the commercial self-insured population.)

$$41,981 \text{ births} \times 42\% = 17,632 \text{ infants in the fully insured population}$$

- b. Number of infant months currently not breastfeeding (receiving human milk from mother): BerryDunn calculated the number of infant months not breastfeeding using a number of methods, and all produced similar answers. A somewhat simplified method is presented in Table 10 and Figure 2 for expositional clarity.
  - Interpolated the percentages for months 1 through 6 for mothers not breastfeeding using CDC data for the percentage of Massachusetts mothers breastfeeding at infant birth, at 2 months, and at 6 months.
  - Multiplied the total number of births (17,632) by the percentage of women not breastfeeding at each month 1 through 6, identifying the estimated number of infants not breastfed at each month interval.
  - Calculated the increment in the number of infants not breastfed by subtracting the prior monthly total from each month.
  - Multiplied the increment in the number of infants by the number of months not breastfed to calculate the infant months.
  - Summed the number of infant months in each monthly interval: 29,313 infant months not breastfed.

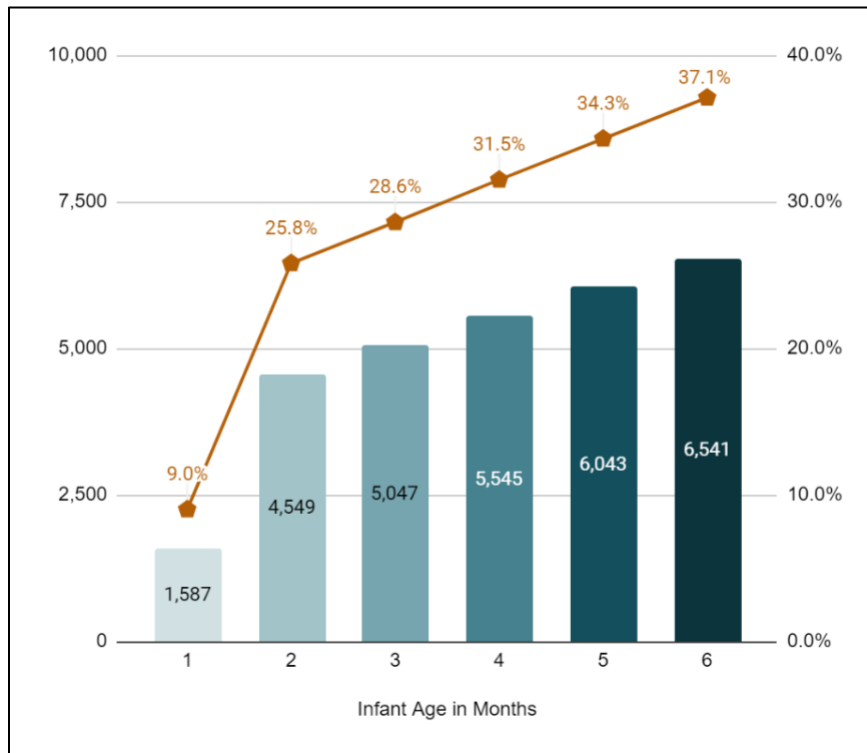


Note: The actual number of infants months annually that rely on DHM will depend on 1) this resulting number of infant months not breastfeeding (Table 10) and 2) the DHM take-up rate during these non-breastfeeding months (further discussed below). The uncertain and potentially wide range of take-up rates among non-breastfeeding mothers/infants will substantially affect the final number of infants, infant months, and associated costs of DHM use—more so than variations in the base number of total infants not breastfeeding in each month.

**Table 10: Total Non-Breastfeeding by Infants under Age Six Months Annually in Massachusetts**

MONTH (MONTHS NOT BREASTFED)	% WHO DO NOT BF <sup>36</sup>	INFANTS IN FULLY INSURED POPULATION	NUMBER OF INFANTS NOT BF	INCREMENT IN NUMBER OF INFANTS NOT BF	# OF INFANT MONTHS NOT BREASTFEEDING (WITHIN THE 6-MONTH ELIGIBILITY PERIOD)
1 (6)	9.0%	17,632	1,587	1,587	9,521
2 (5)	25.8%		4,549	2,962	14,811
3 (4)	28.6%		5,047	498	1,992
4 (3)	31.5%		5,545	498	1,494
5 (2)	34.3%		6,043	498	996
6 (1)	37.1%		6,541	498	498
<b>Infant Months Not BF</b>				<b>6,541</b>	<b>29,313</b>

Figure 2: Number and Percent of Infants Not Breastfeeding



### Average Daily Cost of DHM per Infant per Month

As noted, nonprofit milk banks generally provide their limited supply to medically vulnerable infants in hospital settings and do not provide DHM over an extended period once an infant has been discharged. The provision of DHM to other infants ages up to six months would more likely rely on the commercial sector, with the price per ounce ranging from \$6 to \$10.<sup>37,38</sup> BerryDunn applies an \$8 per ounce price estimate in this analysis.

BerryDunn consulted multiple sources reporting estimates ranging from 8 to 48 ounces per day for infants up to 6 months of age.<sup>39</sup> BerryDunn used an estimation of a range of between 20 and 40 ounces per day for healthy infants receiving DHM. BerryDunn multiplied the number of ounces by the cost per ounce and by 30.4 days per month to calculate the cost per infant per month. Table 11 presents the results.

**Table 11. DHM Cost Per Infant Per Month**

	COST PER OUNCE	NUMBER OF OUNCES PER DAY	COST PER DAY	COST PER MONTH
Low Scenario	\$8.00	20	\$160.00	\$4,867
Mid-Scenario	\$8.00	30	\$240.00	\$7,300
High Scenario	\$8.00	40	\$320.00	\$9,733

BerryDunn multiplied the cost per month in Table 11 by the 2.0% annual increase in the Consumer Price Index (CPI)<sup>40</sup> for food, to estimate the PMPM cost of DHM over the projection period. Table 12 displays these results.

**Table 12. Projected Cost Per Infant Per Month**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$4,867	\$4,964	\$5,063	\$5,165	\$5,268	\$5,373
Mid-Scenario	\$7,300	\$7,446	\$7,595	\$7,747	\$7,902	\$8,060
High Scenario	\$9,733	\$9,928	\$10,127	\$10,329	\$10,536	\$10,746

Table 10 indicates a potential for 29,313 infant months potential for DHM use by the eligible population in a year. The cost per infant per month from Table 12, multiplied by the total number of infant months in a year (29,313), yields the total potential cost per year if DHM were used during all non-breastfeeding months (Table 13).

**Table 13. Projected Cost Per Year, if 100% Use of DHM in all Non-Breastfeeding Months**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$142,657,735	\$145,510,890	\$148,421,108	\$151,389,530	\$154,417,320	\$157,505,667
Mid-Scenario	\$213,986,603	\$218,266,335	\$222,631,661	\$227,084,295	\$231,625,981	\$236,258,500
High Scenario	\$285,315,470	\$291,021,780	\$296,842,215	\$302,779,060	\$308,834,641	\$315,011,334

### ***DHM Take-Up Rate***

The proportion and number of mothers qualifying under Bill Provision 3a that will actually seek to use DHM instead of formula remains uncertain. With insurance coverage available, some mothers who currently or would otherwise use formula may choose to switch to DHM, while others may continue using formula. Several factors could dampen the number of women who will choose DHM. One 2019 study assessed attitudes of postpartum women toward DHM, reporting that that 62% of mothers preferred to use formula over DHM if they were unable to provide their own breast milk.<sup>41</sup> Several factors will affect what proportion of mothers meet the criteria specified in the proposed bill, as “medically or physically unable” to participate and breastfeeding, and who subsequently attain a medical practitioner’s order for insurance coverage of HDM.

For this current analysis, BerryDunn assumes 40% of women would choose DHM. This estimate of potential take-up of the newly covered could vary substantially on either the upside or downside, which would increase or decrease the number of infant months and subsequent cost impact of the covered benefit. BerryDunn multiplied the non-breastfed infant months by the DHM take-up rate to estimate the annual DHM infant months.

**29,313 non-breastfed infant months at 40% DHM take-up rate = 11,725 estimated DHM infant months annually**

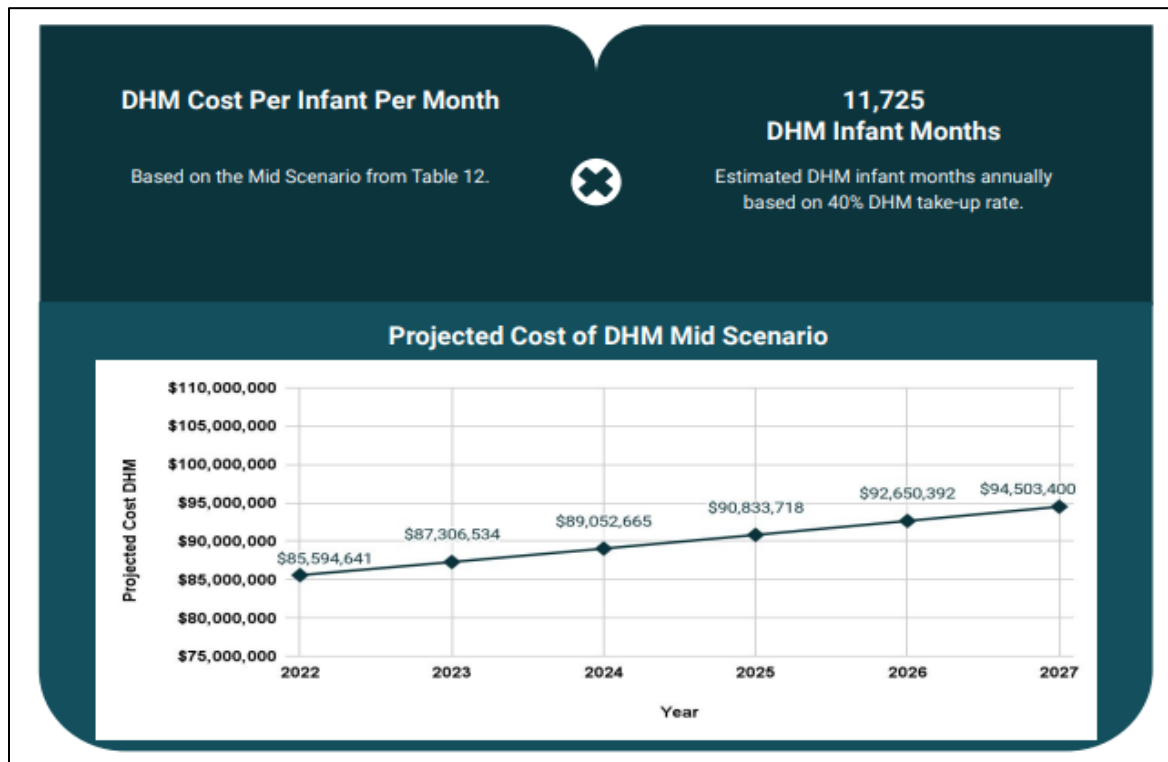
### ***Total Cost and PMPM***

BerryDunn multiplied the DHM cost per infant month from Table 12—by 11,725 DHM infant months annually—to calculate the annual DHM claims cost. Table 14 and Figure 3 present the results.

**Table 14: Projected Cost DHM at an Estimated 40% Take-Up Rate**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$57,063,094	\$58,204,356	\$59,368,443	\$60,555,812	\$61,766,928	\$63,002,267
Mid-Scenario	\$85,594,641	\$87,306,534	\$89,052,665	\$90,833,718	\$92,650,392	\$94,503,400
High Scenario	\$114,126,188	\$116,408,712	\$118,736,886	\$121,111,624	\$123,533,856	\$126,004,533

**Figure 3. Projected Cost of DHM Mid-Scenario**



BerryDunn then divided the claims cost from Table 14 by the corresponding member months to calculate the PMPM cost shown in Table 15.

**Table 15. Projected Cost DHM for Infants Eligible Due to Maternal Factors**

	2022	2023	2024	2025	2026	2027
Low Scenario	\$2.29	\$2.33	\$2.38	\$2.43	\$2.48	\$2.53
Mid-Scenario	\$3.43	\$3.50	\$3.57	\$3.64	\$3.71	\$3.79
High Scenario	\$4.57	\$4.67	\$4.76	\$4.85	\$4.95	\$5.05

### 5.4 Cost Offset for the Removal of Enteral Formulas

In this section, BerryDunn calculates the cost of enteral formulas and the resulting cost offset due to DHM coverage. The availability of DHM will reduce the use of enteral formulas in Massachusetts. Using claims data from the APCD, BerryDunn determined the total cost for enteral formulas for infants. BerryDunn divided the total claims cost for enteral formulas by the total commercial fully insured members to calculate PMPM cost. Table 16 displays the results.

**Table 16. 2020 Cost of Enteral Formulas**

Paid Claims	\$169,948
Member Months	21,441,960
PMPM	\$0.01

The APCD shows 100 enteral formula users. This is about half of the population that is eligible for HMDF. BerryDunn assumed that avoidance in cost of enteral formulas would partially offset the cost of DHM and HMDF. BerryDunn projected the cost of enteral formula over the projection period using the long-term national average projection for cost increases for physician services <sup>42</sup>. Table 17 displays the results.

**Table 17. Estimated Marginal PMPM Cost of Enteral Formulas**

	2023	2024	2025	2026	2027
Low Scenario	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
Mid-Scenario	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01
High Scenario	\$0.01	\$0.01	\$0.01	\$0.01	\$0.01

## 5.5 Marginal Cost PMPM

Adding the estimated PMPM costs associated with DHM for medically needy infants, HMDF, and DHM for the infants qualifying under maternal factors, and subtracting the cost offset from enteral formulas (from Tables 5, 9, 15, and 17) yields the total PMPM marginal cost, shown in Table 18.

**Table 18. Estimated Marginal PMPM Claims Cost of Mandate**

	2023	2024	2025	2026	2027
Low Scenario	\$2.37	\$2.42	\$2.47	\$2.51	\$2.56
Mid-Scenario	\$3.57	\$3.64	\$3.71	\$3.78	\$3.86
High Scenario	\$4.76	\$4.86	\$4.95	\$5.05	\$5.15

## 5.6 Projected Fully Insured Population in the Commonwealth

Table 19 shows the fully insured population in the Commonwealth ages 0 to 64 projected for the next five years. Appendix A describes the sources of these values.

**Table 19. Projected Fully Insured Population in the Commonwealth, Ages 0 – 64**

YEAR	2023	2024	2025	2026	2027
<b>Total (0-64)</b>	2,155,695	2,241,736	2,262,201	2,265,778	2,268,960

## 5.7 Total Marginal Medical Expense

The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2023. Based on an assumed renewal distribution by month, by market segment, and by the Commonwealth market segment composition, 72.1% of the member months exposed in 2023 will have the proposed mandate coverage in effect during calendar year 2023. The annual dollar impact of the mandate in 2023 was estimated using the estimated PMPM and applying it to 72.1% of the member months exposed.

Multiplying the total estimated PMPM cost by the projected fully insured membership over the analysis period results in the total cost (medical expense) associated with the proposed requirement, shown in Table 20.

**Table 20. Estimated Marginal Claims Cost**

	2023	2024	2025	2026	2027
Low Scenario	\$44,223,925	\$65,050,363	\$66,945,913	\$68,380,913	\$69,833,850
Mid-Scenario	\$66,528,035	\$97,863,447	\$100,720,801	\$102,885,766	\$105,078,221
High Scenario	\$88,832,146	\$130,676,532	\$134,495,689	\$137,390,619	\$140,322,592

## 5.8 Carrier Retention and Increase in Premium

Assuming an average retention rate of 14.1%—based on CHIA’s analysis of administrative costs and profit in the Commonwealth<sup>43</sup>—the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 21 displays the result.

**Table 21: Estimate of Increase in Carrier Premium Expense**

	2023	2024	2025	2026	2027
Low Scenario	\$51,507,721	\$75,764,328	\$77,972,080	\$79,643,428	\$81,335,668
Mid-Scenario	\$77,485,377	\$113,981,813	\$117,309,780	\$119,831,321	\$122,384,879
High Scenario	\$103,463,032	\$152,199,298	\$156,647,480	\$160,019,213	\$163,434,090

## 6.0 Results

The estimated impact of the proposed requirement on medical expense and premiums appears in Table 23 below. The analysis includes development of a best estimate “mid-level” scenario, along with a low-level scenario, and a high-level scenario using more conservative assumptions. The impact on premiums is driven by the provisions that carriers cover DHM and human-milk-derived fortifiers (HMDF), and these costs are offset by the lower use (and associated costs) of enteral formulas. Variation between scenarios is attributable to the uncertainty surrounding the number of infants potentially receiving the covered benefit and the length of time that each infant will require DHM and HMDF.

A relatively small number of in-hospital VLBW and LBW infants are born annually and require DHM and HMDF for relatively short time periods, thereby rendering only a small impact on premiums by this segment of the target population. The covered benefit for medically needy in-hospital infants accounts for only 2% of the bill’s estimated marginal premium cost in the mid-scenario. Table 22 displays the relative contributions to the PMPM for 2023, based on the PMPMs reported in Tables 5, 9, 15 and 17, above.

Table 5, above, shows DHM insurance coverage resulting in a first-year (2023) marginal increase from \$0.01 – \$0.03 PMPM; Table 9 shows HMDF insurance coverage resulting in an estimated marginal increase of \$0.04 – \$0.07 PMPM. However, other infants eligible for the covered benefit—those with mothers “medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breastfeeding” — account for approximately 98% of the claims cost in the mid-scenario, with an estimated cost of approximately \$87 million in 2023. (Table 23) The provision of the bill extends coverage to out-of-hospital infants, through age six months, based on a potentially wide range of maternal factors. Through this mechanism, insurance may fund DHM as a substitute for formula for a potentially large number of healthy infants. Table 15, above, shows the DHM insurance coverage results in an estimated first-year marginal increase of \$2.37 – \$4.76 PMPM.

Table 23 displays the relative contribution to total projected claims cost for 2023, by each of the parts of the bills, reported in Tables 4, 8, and 14, above. This includes a cost offset for the reduction in payments for enteral formula, based on the \$169,948 spent in 2020 (Table 16) inflated here to a projection of \$236,194 for 2023.

**Table 22. Projected PMPM Claims Cost, 2023**

	LOW	MID	HIGH
Donor Human Milk – LBW and NEC infants	\$0.01	\$0.02	\$0.03
Human Milk-Derived Fortifier for LBW infants	\$0.04	\$0.05	\$0.07
Donor Human Milk -- months 1-6 based on maternal criteria	\$2.33	\$3.50	\$4.67
Offset – Reduction in payments for enteral formula	<\$0.01 >	<\$0.01 >	<\$0.01 >
<b>Total</b>	<b>\$2.37</b>	<b>\$3.57</b>	<b>\$4.76</b>



**Table 23. Total Projected Claims Cost, 2023**

	LOW	MID	HIGH
Donor Human Milk – LBW and NEC infants	\$277,888	\$555,777	\$833,665
Human Milk-Derived Fortifier for LBW infants	\$913,410	\$1,370,115	\$1,826,820
Donor Human Milk -- months 1-6 based on maternal criteria	\$58,204,356	\$87,306,534	\$116,408,712
Offset – Reduction in payments for enteral formula	<\$236,194>	<\$236,194>	<\$236,194>
<b>Total</b>	<b>\$59,159,460</b>	<b>\$88,996,231</b>	<b>\$118,833,002</b>

### 6.1 Five-Year Estimated Impact

For each year in the five-year analysis period, Table 24 displays the projected net impact of the proposed language on medical expense and premiums using a projection of Commonwealth fully insured membership. The relevant provisions are assumed effective January 1, 2023.<sup>44</sup> Low, medium, and high scenarios vary in the estimated number of ounces per day of DHM that infants might consume, and the estimates also account for eligibility for and take-up of the covered benefit. The low scenario would result in \$77.4 million per year on average. The high scenario's projected impact is \$155.5 million. The mid-scenario would result in average annual costs of \$116.5 million, or an average of 0.73% of premiums.

Figures in Table 24 differ from reference tables in Section E, and in Tables 22 and 23, because reference tables in Section 5 reflect dollars based on a membership snapshot used in the development of the PMPMs. Table 24 displays projected membership based on a population projection, as summarized in Table 18. The Table 24 summary table also applies a 72% adjustment factor to the first-year (2023) implementation to account for ramp up in implementation.

Finally, the impact of the proposed law on any one individual, employer group, or carrier may vary from the overall results, depending on the current level of benefits each receives or provides, and on how the benefits will change under the proposed language.

**Table 24. Summary Results**

	2023	2024	2025	2026	2027	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
Average Members (000s)	2,156	2,242	2,262	2,266	2,269		
Medical Expense Low (\$000s)	\$44,224	\$65,050	\$66,946	\$68,381	\$69,834	\$66,458	\$314,435
Medical Expense Mid (\$000s)	\$66,528	\$97,863	\$100,721	\$102,886	\$105,078	\$99,987	\$473,076
Medical Expense High (\$000s)	\$88,832	\$130,677	\$134,496	\$137,391	\$140,323	\$133,517	\$631,718
Premium Low (\$000s)	\$51,508	\$75,764	\$77,972	\$79,643	\$81,336	\$77,403	\$366,223
Premium Mid (\$000s)	\$77,485	\$113,982	\$117,310	\$119,831	\$122,385	\$116,455	\$550,993
Premium High (\$000s)	\$103,463	\$152,199	\$156,647	\$160,019	\$163,434	\$155,508	\$735,763
PMPM Low	\$2.76	\$2.82	\$2.87	\$2.93	\$2.99	\$2.88	\$2.88
PMPM Mid	\$4.15	\$4.24	\$4.32	\$4.41	\$4.49	\$4.33	\$4.33
PMPM High	\$5.55	\$5.66	\$5.77	\$5.89	\$6.00	\$5.79	\$5.79
Estimated Monthly Premium	\$562	\$577	\$593	\$609	\$625	\$593	\$593
Premium % Rise Low	0.491%	0.488%	0.484%	0.481%	0.478%	0.486%	0.486%
Premium % Rise Mid	0.739%	0.734%	0.729%	0.724%	0.719%	0.731%	0.731%
Premium % Rise High	0.987%	0.980%	0.973%	0.966%	0.960%	0.976%	0.976%

## 6.2 Impact on GIC

The proposed mandate would apply to self-insured plans operating for state and local employees by the Group Insurance Commission (GIC). The benefit offerings of GIC plans are similar to most other commercial plans in Massachusetts. This section describes the results for the GIC.

Findings from BerryDunn's carrier survey indicate that benefit offerings for GIC and other commercial plans in the Commonwealth are similar. For this reason, the cost of Senate Bill 717 for GIC will likely be similar to the cost for other fully insured plans in the Commonwealth.

BerryDunn assumed the proposed legislative change will apply to self-insured plans that the GIC operates for state and local employees, with an effective date of July 1, 2023. Because of the July effective date, the results in 2023 are approximately one-half of an annual value. Table 25 breaks out the GIC's self-insured membership and the corresponding incremental medical expense.

**Table 25. GIC Summary Results**

	2023	2024	2025	2026	2027	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
<b>GIC Self-Insured</b>							
Members (000s)	312	312	311	311	310		
Medical Expense Low (\$000s)	\$4,444	\$9,047	\$9,210	\$9,374	\$9,543	\$9,252	\$41,619
Medical Expense Mid (\$000s)	\$6,686	\$13,611	\$13,857	\$14,105	\$14,359	\$13,921	\$62,617
Medical Expense High (\$000s)	\$8,927	\$18,175	\$18,503	\$18,835	\$19,175	\$18,589	\$83,615

## Endnotes

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<sup>1</sup> The 192<sup>nd</sup> General Court of the Commonwealth of Massachusetts, House Bill 1106 and Senate Bill 717, “An Act Relative to Human Donor Milk Coverage.” Accessed July 29, 2022: <https://malegislature.gov/Bills/192/H1106> and <https://malegislature.gov/Bills/192/S717>.

<sup>2</sup> The bill, as currently written, does not include Chapter 176A. However, the Sponsors confirmed that the bill’s intent is to include Chapter 176A.

<sup>3</sup> M.G.L. c.175 §471. Accessed September 26, 2022.  
<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section471>.

<sup>4</sup> *Op. cit.* Interviews and email communication with Drs. Margaret Parker and Sarah Taylor.

<sup>5</sup> New Jersey Office of Legislative Services. Legislative Fiscal Estimate. Senate, No. 3159. State of New Jersey 2018<sup>th</sup> Legislature. March 22, 2019. Accessed September 9, 2022.  
[https://pub.njleg.state.nj.us/Bills/2018/S3500/3159\\_E1.PDF](https://pub.njleg.state.nj.us/Bills/2018/S3500/3159_E1.PDF).

<sup>6</sup> Carroll K, Herrmann KR. The cost of using donor human milk in the NICU to achieve exclusively human milk feeding through 32 weeks postmenstrual age. *Breastfeed Med.* 2013 Jun;8(3):286-90. Accessed September 14, 2022.  
<https://doi.org/10.1089/bfm.2012.0068>.

<sup>7</sup> *Op cit.* Cohen M. *Regulating Milk: Women and Cows in France and the United States.*

<sup>8</sup> *Op. cit.* Carroll K, Herrmann KR. *The cost of using donor human milk in the NICU to achieve exclusively human milk feeding through 32 weeks postmenstrual age.*

<sup>9</sup> Rocky Mountain Children’s Health Foundation. FAQ: Buying Milk. (“A newborn baby typically consumes about one ounce per feeding, and there are usually around eight feedings in one day.”). Accessed September 22, 2022.  
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## Appendix A: Membership Affected by the Proposed Language

Membership potentially affected by proposed mandated change criteria includes Commonwealth residents with fully insured, employer-sponsored health insurance issued by a Commonwealth-licensed company (including through the GIC); nonresidents with fully insured, employer-sponsored insurance issued in the Commonwealth; Commonwealth residents with individual (direct) health insurance coverage; and lives covered by GIC self-insured coverage. Other populations within the self-insured commercial sector are excluded from the state coverage mandate due to federal ERISA protections of self-insured plans.

The unprecedented economic circumstances due to COVID-19 add particular challenges to estimation of health plan membership. The membership projections are used to determine the total dollar impact of the proposed mandate in question; however, variations in the membership forecast will not affect the general magnitude of the dollar estimates. Given the uncertainty, BerryDunn took a simplified approach to the membership projections. These membership projections are not intended for any purpose other than producing the total dollar range in this study. Further, to assess how recent volatility in commercial enrollment levels might affect these cost estimates, please note that the PMPM and percentage of premium estimates are unaffected because they are per-person estimates, and the total dollar estimates will vary by the same percentage as any percentage change in enrollment levels.

The 2018 Massachusetts APCD formed the base for the projections. The Massachusetts APCD provided fully insured membership by insurance carrier. The Massachusetts APCD was also used to estimate the number of nonresidents covered by a Commonwealth policy. These are typically cases in which a nonresident works for a Commonwealth employer that offers employer-sponsored coverage. Adjustments were made to the data for membership not in the Massachusetts APCD, based on published membership reports available from CHIA and the Massachusetts Division of Insurance (DOI).

CHIA publishes monthly enrollment summaries in addition to its biannual enrollment trends report and supporting databook (enrollment-trends-Data Through September 2021 databook<sup>1</sup> and Monthly Enrollment Summary – June 2021<sup>2</sup>), which provide enrollment data for Commonwealth residents by insurance carrier for most carriers, excluding some small carriers. CHIA uses supplemental information beyond the data in the Massachusetts APCD to develop its enrollment trends report and adjust the resident totals from the Massachusetts APCD.

The DOI published reports titled Quarterly Report of HMO Membership in Closed Network Health Plans as of December 31, 2018,<sup>3</sup> and Massachusetts Division of Insurance Annual Report Membership in Medical Insured Preferred Provider Plans by County as of December 31, 2018.<sup>4</sup> These reports provide fully insured covered members for licensed Commonwealth insurers where the member's primary residence is in the Commonwealth. The DOI reporting includes all insurance carriers and was used to supplement the Massachusetts APCD membership for small carriers not in the Massachusetts APCD.

In 2021, commercial, fully insured membership was 5.6% less than in 2019, with a shift to both uninsured and MassHealth coverage. As part of the public health emergency (PHE), members were not disenrolled from MassHealth coverage, even when they no longer passed eligibility criteria. When the PHE ends, redetermination efforts will begin at which time these individuals will no longer be eligible for MassHealth coverage. It is anticipated that a portion of individuals losing coverage will be eligible for coverage in individual ACA plans. Although the impact



of COVID-19 on the fully insured market over the five-year projected period (2023 – 2027) is uncertain, BerryDunn has made the following assumptions to estimate membership:

The federal PHE will end in 2023

Redetermination will occur over 12 months for MassHealth members<sup>5</sup>

MassHealth members will be eligible for commercially insured plans

BerryDunn assumes 80% of the commercial membership reductions that occurred during the PHE will return to the commercial market by the end of 2023. BerryDunn further assumes that the remainder of this membership will return to the commercial market by the end of the projection period in December of 2027.

The distribution of members by age and gender was estimated using Massachusetts APCD population distribution ratios and was checked for reasonableness and validated against U.S. Census Bureau data.<sup>6</sup> Membership was projected from 2022 – 2027 using Massachusetts Department of Transportation population growth rate estimates by age and gender.<sup>7</sup>

Projections for the GIC self-insured lives were developed using the GIC base data for 2018 and 2019, which BerryDunn received directly from the GIC, as well as the same projected growth rates from the Census Bureau that were used for the Commonwealth population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

## Appendix A Endnotes

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