

## PERSPECTIVE



## US state policies for Medicaid coverage of donor human milk

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Donor human milk is recommended by the American Academy of Pediatrics for high-risk infants when mother's own milk is absent or insufficient in quantity. Several factors may contribute to the inequitable use of or access to donor human milk, including a limited knowledge of its effects, cost, reimbursement, and regulatory barriers. The American Academy of Pediatrics and the United States Surgeon General have called for investigating barriers that prevent use of donor human milk for high-risk infants and for changes to public policy known to improve availability and affordability. We review the current legislative, regulatory, and economic landscape surrounding donor human milk use in the United States, as well as suggest state- and federal-level solutions to increase access to donor human milk.

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## INTRODUCTION

Human milk is the ideal diet for infants and is associated with beneficial health outcomes [1–3]. These benefits are especially potent for very premature (<32 weeks gestation) and very low birth weight (VLBW) infants (birth weight <1500 g) [4]. A clear protective effect against necrotizing enterocolitis (NEC), a devastating disease that affects the intestines of premature and other high-risk infants, has been demonstrated in multiple studies, such that if maternal milk is absent or insufficient in quantity, the use of donor human milk (DHM) is recommended [2, 4–8]. The American Academy of Pediatrics (AAP) recommends that DHM be used in high-risk infants when mother's milk is insufficient in quantity, and that DHM be available based on medical necessity, not financial status [7]. The recommendation for pasteurized DHM when mother's own milk is not available, is insufficient in quantity, or is contraindicated, was also noted in an AAP Clinical Report focused on human milk for VLBW infants [9].

## WHAT IS DONOR HUMAN MILK AND WHO NEEDS IT?

DHM is human milk that has been donated by healthy lactating individuals, then processed and distributed in accordance with established evidence-based guidelines [7, 10]. The first donor milk organization in North America was established in 1910 as the Boston Wet Nurses Directory, which then became a donor milk bank in 1919 [11]. DHM has been used in premature and ill infants for over 100 years when mother's milk has been insufficient in quantity or unavailable. Human milk contains bioactive factors such as immunoglobulins, human milk oligosaccharides, lysozyme, lactoferrin and other factors that are important to immune and intestinal development and protect against inflammatory disorders, such as NEC [6, 12].

Meta-analysis of randomized controlled trials supports the use of DHM instead of formula in preterm infants. A 2019 Cochrane

review found that feeding premature or low birthweight infants formula rather than DHM is associated with a near-doubled NEC risk (Risk Ratio 1.87, 95% CI 1.23–2.85, 9 studies, 1675 infants) [8]. A contemporary large blinded randomized controlled trial from Canada found a reduction in the rate of NEC from 6.6% to 1.7% when comparing preterm formula to DHM fortified with powdered bovine-based fortifier [13].

Outside of prematurity status, other neonatal conditions such as gastrointestinal anomalies and congenital heart disease may place an infant at high risk for feeding complications, including NEC. Evidence to support the use of DHM in these high-risk populations is limited to observational studies [14–17]. While DHM use is typically restricted to very premature and VLBW infants on the basis of the available evidence showing benefit in this population and cost-effectiveness, individual hospital policy typically determines which infants may receive DHM, and criteria vary widely [18]. Local patterns of use also help determine the cost-effectiveness of DHM use, which is dependent on several factors, including the rate mothers provide their own milk, cost and source of DHM, number of eligible infants, and duration of use. DHM use in VLBW infants may be cost-saving or cost-neutral from the decreased incidence of NEC and shorter hospital stay, which offset the initial investment [19–23]. In addition, those savings may extend beyond hospital discharge; an economic analysis of a randomized controlled trial of comparing health outcomes on VLBW infants fed DHM versus preterm formula demonstrated infants who were fed DHM had decreased post-discharge costs, likely related to lower parental lost wages [23].

## BARRIERS TO DONOR HUMAN MILK ACCESS AND USE

Although extensive evidence supports the use of DHM in VLBW infants, availability of DHM is a healthcare disparity. DHM use varies by level of care, ranging from 18% of level 1 nurseries to

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66% of level 3 and 74% of level 4 units which typically care for post-surgical neonates [20, 24–27]. Safety-net hospitals ( $\geq 75\%$  Medicaid) and hospitals with a high proportion of Black or Hispanic patients are less likely to use DHM compared to non-safety-net hospitals [24, 26, 28]. These differences are not fully explained by lack of supply or geography, as the Human Milk Banking Association of North America (HMBANA), which accredits nonprofit milk banks in the United States and Canada, has 31 active milk bank members and four more in development. The capacity to dispense DHM continues to increase annually, and DHM is routinely shipped overnight to and from milk banks regionally and nationally [29].

Both the AAP and the Surgeon General have called for investigation into the barriers that prevent the use of DHM and for changes to policy to improve availability and affordability [7, 30]. We review the current legislative, economic, and regulatory landscape surrounding DHM use in the US, describe how limitations of current policies create barriers to care, and suggest solutions to improve access to DHM for vulnerable infants. Understanding current state policies and regulations can assist advocates in leveraging policy tools to facilitate access to DHM for infants who could most benefit.

## REVIEW OF STATE LEGISLATIVE AND REGULATORY POLICIES FOR DONOR HUMAN MILK

After using the commercial legal database, Westlaw, as well as state-government websites to identify enacted statutes and regulations that included direct reference to DHM, we evaluated the results regarding DHM provision and insurance reimbursement (search strategy available in Supplementary Table 1). We compared approaches of all states identified with regards to their DHM coverage policies including public versus commercial insurance reimbursement, varying definitions of medical necessity, patient age limits, and inpatient versus outpatient benefit.

At the time of this manuscript submission, 14 states and the District of Columbia have enacted DHM legislation or regulations addressing Medicaid or commercial insurance coverage (Table 1). California was the first to approve Medicaid reimbursement for DHM in 1998. Since then, advocates have worked to increase DHM access [10, 31]. Over half of the existing state-level policies have been enacted since the 2017 publication of the AAP Policy on DHM [7]. Nine states pursued legislative mandates, while five and the District of Columbia created coverage through state regulatory measures. Since 2020, seven additional states have introduced legislation for DHM coverage, including Georgia, Maine, Massachusetts, Nevada, Oklahoma, South Carolina, and Virginia. Although it is unlikely that all of these efforts will result in enacted legislation, they represent important ongoing state level advocacy.

The DHM legislation or regulations vary widely. Age limits for coverage are different between states, with Missouri and Kansas the most restrictive, covering DHM until 3 months of age, and Texas allowing for outpatient DHM up to 20 years, although this is an extreme exception. The availability of mother's own milk is another variable, with New Jersey allowing for an infant up to 6 months of age to receive DHM if mother's own milk is generally insufficient in quantity or unavailable, while the District of Columbia lists reasons a mother is unable to provide milk, including due to illness, death, surgery, chronic condition, drug, or medication use. Missouri does not explicitly require unavailability or inadequate supply of mother's own milk and New York also includes language that the mother had optimal lactation support. Medical necessity is defined variably. Some states, such as Connecticut, include a requirement of "medical necessity," relying on a broader definition of medical necessity that applies to all Medicaid treatment, for example. Others, such as Illinois, list specific medical conditions to be considered in the context of ordering DHM for a VLBW infant.

State law insurance reimbursement requirements are limited to Medicaid in many states; in New York, Medicaid coverage was mandated in 2017 and then subsequent statutes passed in 2018 required coverage by all insurance providers. Regulations in Illinois, Kentucky, and New Jersey also include commercial insurance coverage requirements. Kentucky is unique in that it requires coverage for human milk-based fortifier as part of an exclusive human milk diet for commercial plans but includes no Medicaid requirements [32]. South Carolina does not have a statewide policy, however Select Health, one of the state's managed Medicaid plans, began covering DHM in 2016 [33]. It is possible that other states have similar unique situations where individual plans have implemented a DHM benefit without broader coverage by Medicaid.

Coverage for DHM within Medicaid programs is uniquely suited to improve access for premature and other high-risk infants. Medicaid covers approximately 40% of all US births and 50% of all early preterm births [34]. It also covers a disproportionate share (59–65%) of Hispanic and Black infants, who are more likely to be born in safety-net hospitals and who may be more likely to develop NEC associated with reduced human milk use [35, 36].

Figure 1 shows the percentage of VLBW infants born in states with any form of DHM policy from 2009–2019. In 2009, 6144 (11%) VLBW infants were born in a state with a DHM policy. In 2019, that number increased to 20,145 (43%). However, these numbers may be an overrepresentation of covered infants based on the policy differences discussed above and in Table 1. Over half of VLBW infants are born in the 35 states without DHM coverage, and thus some of these infants may lack access to this intervention. Interestingly, if all DHM bills proposed in state legislatures in 2020 and 2021 become law, an additional estimated 4300 VLBW infants would have potential access to DHM, representing, in addition to those already covered, an estimated 53% of all VLBW infants in the US.

## FEDERAL LAW AND POLICY

There is federal precedent to support breastfeeding and the use of human milk even prior to the Patient Protection and Affordable Care Act (ACA) [37]. However, the ACA substantially strengthened breastfeeding policies, requiring insurance plans to provide breastfeeding support, counseling, and equipment [38]. As well, the ACA requires dedicated space for breastfeeding and mandatory break time for pumping for hourly-wage working mothers, impacting upwards of 19 million women [39, 40]. However, few federal policies explicitly address the provision of DHM.

The Special Supplemental Nutrition Program for Women Infants and Children (WIC) is a federal program for which eligibility is determined by the federal government based on participant category (pregnant, postpartum, breastfeeding, infant or child up to age 5), income and nutritional risk [41]. WIC program regulations require local WIC agencies to create policies to support breastfeeding, especially for women who are most likely to need assistance [42]. Prior to 2000, WIC allowed the use of DHM on a case by case basis; however in 2000 the agency prohibited DHM as an allowable substitute for WIC-eligible formulas citing the lack of federal health and safety standards for milk banking operations, lack of mandatory pathogen, drug and toxin screening, and the alteration to the nutritive value of human milk by the pasteurization process as the key drivers for its policy change [43]. Current medical evidence, including safety shown in multiple clinical trials, have mitigated these concerns for DHM use in VLBW or preterm infants. In addition, a 2011 Food and Drug Administration public advisory committee meeting stated that the "processing adopted by the Human Milk Banking Association of North America and Prolacta, a commercial vendor of human milk products, appears to control the [infectious disease] risks adequately" [44].

**Table 1.** State statutes and regulations regarding donor human milk<sup>a</sup>.

State/District, Effective year	Plans	Medical conditions covered	Age limits	Prior Auth	Informed consent	Outpatient benefit	Inpatient benefit
California, 1998	Medicaid	Mother unable to breastfeed and infant cannot tolerate or has a contraindication to formula	Silent <sup>b</sup>	Silent	Silent	Silent	Silent
Connecticut, 2019	Medicaid	Documented medical necessity. State to adopt or amend regulations for implementation.	Set by state	Silent	Silent	Silent	Silent
Illinois, 2020	Medicaid + Commercial	One of: 1) birth weight <1500 g, 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 mo, recipient must have SMA.	12 mo <sup>c</sup>	Silent	Silent	Yes	Silent
Kansas, 2015	Medicaid	Critically ill infant in NICU. DHM prescribed by an authorized individual. State determines medical necessity. Milk bank meets state standards.	3 mo	Yes	Yes	No	Yes
Kentucky, 2013	Commercial	Prescribed for the prevention of NEC and associated comorbidities. Prescribed by a physician. <sup>d</sup>	Silent	Silent	Silent	Silent	Silent
Louisiana, 2020	Medicaid	One of: 1) prematurity, 2) malabsorption, 3) feeding intolerance, 4) immunologic deficiency, 5) congenital heart disease, 6) other congenital anomalies, 7) high risk of NEC. Optimal lactation support provided. Education on DHM provided. Milk bank accredited by HMBANA.	12 mo	Silent	Silent	No	Yes
Missouri, 2014	Medicaid	Critically ill infant in NICU. DHM prescribed by an authorized individual. State determines medical necessity. Milk bank meets state standards.	3 mo	Yes	Yes	No	Yes
New Jersey, 2019	Medicaid + Commercial	One of: 1) infant unable to receive maternal milk or mother unable to produce or produce sufficient milk, or 2) infant meets any of the following: a) body weight below healthy levels, b) high risk of NEC, c) congenital or acquired condition that may benefit from DHM as determined by the state. Milk bank meets state standards.	6 mo	Utilization review	Silent	Silent	Silent
New York, 2017 <sup>e</sup>	Medicaid + Commercial	One of 1) <1500 g at birth 2) high risk for NEC 3) other condition that may benefit from DHM, determined by state.	Silent	Silent	Silent	No	Yes
Ohio, 2018	Medicaid	Documented medical necessity.	Silent	Silent	Silent	Yes	Silent
Oregon, 2019	Medicaid	Must have all: 1) birth weight <1500 g or severe underlying gastrointestinal disease; 2) DHM continued through neonatal hospital discharge for medical indications 3) Persistent outpatient medical need 4) maternal breast milk not available or insufficient. Milk bank accredited by HMBANA.	6 mo	Silent	Silent	Yes	No
Pennsylvania, 2017	Medicaid	Medical necessity determined based on most up to date American Academy of Pediatric clinical guidelines. Milk bank certified by HMBANA.	Silent	Yes	Silent	Yes	No
Texas, 2003	Medicaid	Documented medical necessity. Bank meets HMBANA standards or other standards adopted by the state.	6/11 mo <sup>f</sup>	Yes	Yes	Yes	Yes
Utah, 2018	Medicaid	DHM is medically necessary. Mother cannot provide milk.	11 mo	Yes	Yes	Yes	No

Table 1. continued

State/District, Effective year	Plans	Medical conditions covered	Age limits	Prior Auth	Informed consent	Outpatient benefit	Inpatient benefit
District of Columbia, 2017	Medicaid	One of: 1) infant is fragile, 2) premature or 3) medically compromised. Mother cannot breastfeed due to illness, death, surgery, chronic condition, drug or medication use. Documented medical necessity. Documented feeding trial every 180 days.	12 mo	Yes <sup>9</sup>	Yes	Yes	Yes

NEC necrotizing enterocolitis, SMA spinal muscular atrophy, NICU neonatal intensive care unit, DHM donor human milk, HMBANA Human Milk Banking Association of North America.

<sup>a</sup>See Supplementary Table 1 for individual state statutes and regulation citations.

<sup>b</sup>Silent means the statute or regulation does not specifically address the topic and additional policy documentation was not identified for further clarification.

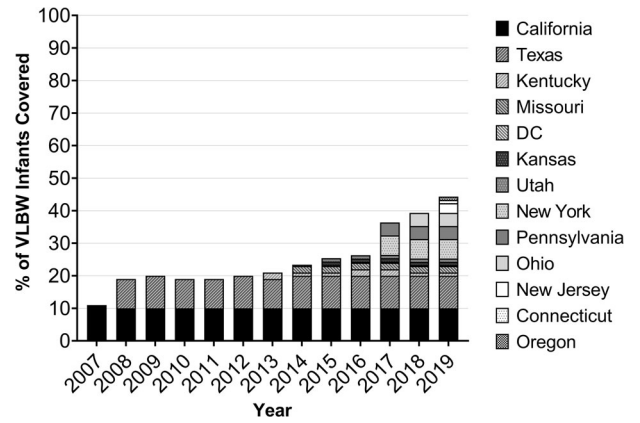
<sup>c</sup>Only Medicaid covers >12 mo.

<sup>d</sup>Coverage is for 100% human milk diet with an inflation adjusted \$15,000 per year per infant.

<sup>e</sup>Medicaid required in 2017, all other providers in 2018.

<sup>f</sup>Inpatient coverage up to 6 mo. Outpatient coverage up to 11 mo. Can have exceptions for up to 20 years.

<sup>9</sup>Renewed every 90 days; expires on 1st birthday.



**Fig. 1 Percent of very low birth weight infants born in a state with a donor human milk policy.** Percent of VLBW infants born each year in a state with any form of donor human milk policy (inpatient coverage, outpatient coverage, or both) was calculated using CDC Wonder Natality database from 2007 to 2019 [52]. The numerator for each year is the number of live born infants with BW < 1500 g in a state with a DHM policy. The denominator is the total number of infants born in the US with birth weight <1500 g for the given year. VLBW from Louisiana and Illinois are not included as CDC Wonder Natality is current through 2019, and coverage was not required until 2020.

TriCare, the federal health care program for uniformed service members, retirees, and their families around the world, however, takes a different approach. Tricare changed its coverage to cover the use of DHM up to 12 months of age starting in 2019 [45]. However, plans within Tricare implement this benefit in a variety of ways, with some members required to cover initial expenses out-of-pocket prior to reimbursement, placing a potentially large financial burden on families that may prohibit access.

**STEPS TO ADVANCE ACCESS TO DONOR HUMAN MILK**

We believe there are four critical steps necessary to improve access to DHM.

**Engaging key stakeholders**

Key stakeholders, including families of high-risk infants, patients impacted by diseases such as NEC, healthcare professionals, and policy makers, must be engaged and educated on the benefits of DHM. Lactation education for healthcare professionals should include the evidence base for DHM and the production pipeline and accessibility of DHM so they can communicate clearly with patient families regarding risks and benefits to better inform consent. Families should have access to education about DHM, as well as information on how to donate milk for those who are able. Potential donors can visit the HMBANA website ([www.hmbana.org](http://www.hmbana.org)) for guidance about the screening process, including health questionnaires, medical clearance, and blood testing.

**Policy changes**

Policies at the hospital, state and federal level can support the use of DHM in appropriate high-risk infants. Hospitals that provide infants in the neonatal intensive care unit access to DHM have seen associated increases in mother’s milk use as this may enhance the recognized value of human milk to infant health [20, 46, 47]. Advocacy efforts from the child health community can draw on successes from states with current DHM policies to overcome the lack of awareness of the benefits of DHM among policy makers as well as hesitancy about increased short-term spending from fiscally wary administrators and legislatures.

Medically necessary DHM should be covered and reimbursed by state Medicaid plans and commercial insurance. DHM, as a benefit,

should seamlessly be covered for inpatient as well as outpatient use in certain high-risk conditions. Many infants with conditions such as gastroschisis, intestinal failure, or severe congenital heart disease have complex nutritional needs after discharge from a neonatal unit, and their access to DHM should continue at home, if deemed appropriate for their nutritional needs by their treating clinicians. DHM advocates can work collaboratively on the state level, either through the legislative process or directly with state health agencies, to advance policies that support DHM as an explicit part of policies that promote breastfeeding and lactation, as they are all inextricably linked.

The most inclusive approach would involve federal legislation requiring that DHM be a fully covered benefit by all insurance policies. Important beyond DHM coverage are additional federal policies that support breastfeeding such as those implemented in the ACA. Mothers establishing lactation for VLBW infants, who are unable to directly breastfeed, must have access to NICU-specific lactation expertise as well as high-quality, hospital grade breast-pumps. The AAP recommends effective and efficient double electric breast pumps for mothers of VLBW infants to maximize and maintain milk expression at the hospital and at home [9]. Policies that more broadly support families, including paid family leave, ensuring a livable wage through universal basic income or raising the minimum wage, and housing and educational support would also help mediate the economic burden associated with the provision of mother's own milk [39, 48]. Similarly, since previously cited concerns regarding the safety of DHM have been adequately addressed, including DHM as a WIC-eligible specialty nutritional product, when medically indicated, would increase access for low-income families, further reducing disparities in DHM availability. While the potential for expanding the use of DHM must be balanced with the supply of DHM, HMBANA now has 31 participating milk banks and reported record-breaking donation volumes in 2020 despite the COVID-19 pandemic [29].

Just as important as advocating for policies that improve health, is ensuring that those policies are implemented, and practices adjusted. Additionally, policies that lack appropriate funding will be ineffective. Funds should be appropriated as part of the original legislative or regulatory mandate. Policy implementation should be simple and streamlined to reduce barriers for hospitals and make verification of use and payment easy for Medicaid agencies. Further, implementation efforts of state policies should include a periodic reassessment by Medicaid agencies to determine the potential cost-savings of DHM and consider revision of the indications for use and payment based on established medical evidence. State and local chapters of organizations such as the AAP have government relations committees and other structures in place that may be able to assist local advocates' efforts.

### Funding for research and milk banks

Funding to support human milk research and milk bank creation and maintenance is needed. Research funding may support the study of human milk, including approaches to maximally preserve beneficial nutrients and bioactive factors in DHM after processing, and evaluate the evidence for DHM use in high-risk infant populations outside of those born prematurely. Funding could also support the creation and maintenance of new non-profit milk banks. Recent legislation passed in Arkansas created a state-funded milk bank, an action that will directly benefit infants in that state [49]. The infant mortality rate in Arkansas is higher than most other states in the country, and creation of a state milk bank may increase access to DHM availability for hospitalized infants in Arkansas.

### Advocacy

Finally, DHM advocacy efforts are critically important and require institutional and financial support. Evidenced-based medicine should be central in the creation of health and social policy, and

child advocates need support in their efforts to advocate and educate for improved health outcomes [50]. Advocacy and policy education can be incorporated into medical training programs to give future physicians the tools necessary to effectively influence child health policy [51]. DHM advocates can network with colleagues in states with successful DHM regulations to adapt advocacy approaches and enact change in their own state. From initial discussions through the final passage of a bill or policy, the legislative process can take years. Importantly, effective implementation of adopted policy will also need additional advocacy efforts. Philanthropic funding and grant support can sustain policy research, development, and implementation and allow volunteer advocates to build networks and enact change.

While it may seem challenging to begin advocating, but many others have gone through the process. In the authors' experience, we have found it very helpful to connect with other states and groups to discuss strategies and tools for advocacy. For those interested in new advocacy efforts, you might reach out to the corresponding author for more information.

### CONCLUSION

The majority of high-risk infants who need access to DHM are not born in a state or district where that access is guaranteed; no state currently covers the cost of DHM whether inpatient, outpatient, or for all infants who may benefit from its use. State and federal level advocacy is needed to ensure that DHM is available to all infants based on medical necessity, rather than privileging infants who happen to be born in a state or district where access is guaranteed. High-risk infants would particularly benefit from legislative and regulatory changes that would increase patient access to and affordability of DHM, including mandated coverage.

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## AUTHOR CONTRIBUTIONS

SIS and RMP conceived the manuscript subject. ATR and ERM equally contributed to the main conceptual ideas, drafted the manuscript with contribution and critical revisions from all authors. MB devised the legal search strategy, reviewed, collated, and interpreted results. All authors discussed the results, edited, and approved the final manuscript.

## COMPETING INTERESTS

RMP and ATR receive salary support from the NEC Society for a PCORI-funded capacity-building and research prioritization award on NEC. RMP serves on the data monitoring committee for IBT Therapeutics and Premier Research. JHK is a paid consultant for Fujifilm and serves as a medical advisor for Medela. He is on the Board of Directors for Innara Health and owns shares in Astarte Medical and Nicolette. All other authors declare no competing interests.

## ADDITIONAL INFORMATION

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