

HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 1333 Donor Human Milk Bank Services
SPONSOR(S): Finance & Facilities Subcommittee, McFarland and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1770

FINAL HOUSE FLOOR ACTION: 117 Y's 0 N's **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 1333 passed the House on March 8, 2022, as CS/SB 1770.

Breast milk is the best source of nutrition for most infants. Ideally, an infant should be fed his or her own mother's breast milk. Mothers of infants born prematurely are sometimes unable to produce milk because their bodies aren't ready, they too are sick, or they're affected by the stress of having their premature infant in intensive care. Breast milk donated by nursing mothers provides an option in such instances. Very few illnesses are transmitted via breast milk, even in cases of donated milk.

Human donor breast milk can be effective for high-risk and very low birthweight infants if the child's mother is unable to provide enough milk. Authorities indicate that human donor breast milk can prevent some digestive disorders but specify that any donor milk must come from safe facilities and is not recommended for sick infants or those weighing less than 1,000 grams. Currently, the federal Food and Drug Administration considers human donor breast milk a food source rather than a medical product and does not regulate human donor milk banks.

The Medicaid program is a joint federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults and persons with disabilities. Florida Medicaid reimburses hospitals for inpatient use of infant nutritional supplementation through an all-inclusive payment to the hospital, and outpatient prescription nutritional commercial formulas under the durable medical equipment and supplies benefit. Human donor breast milk is not a covered benefit in the Medicaid program.

The bill authorizes Medicaid reimbursement for donor human milk for hospital inpatient use. The Medicaid coverage would be for infants who are medically or physically unable to receive maternal breast milk or whose mother medically or physically unable to produce maternal breast milk or breastfeed, and who also meet specified clinical eligibility factors.

The bill has an insignificant recurring negative fiscal impact on AHCA, and no fiscal impact on local governments.

The bill was approved by the Governor on April 6, 2022, ch. 2022-40, L.O.F., and will become effective on July 1, 2022.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Donor Human Breast Milk

According to the federal Centers for Disease Control and Prevention (CDC), breast milk is the best source of nutrition for most infants.¹ Ideally, an infant should be fed his or her own mother's breast milk because nutritional components within the mother's breast milk change to meet the infant's needs as he or she ages.² Mothers of infants born prematurely are sometimes unable to produce milk because their bodies aren't ready, they too are sick, or they're affected by the stress of having their premature infant in intensive care. Breast milk donated by nursing mothers provides an option for infants who are unable to receive adequate nutrition from their mother's own milk or from commercial infant formulas. Very few illnesses are transmitted via breast milk, even in cases where someone else's breast milk is given to another child.³

The American Academy of Pediatrics (AAP) notes that human donor breast milk can be effective for high-risk and very low birthweight infants if the child's mother is unable to provide enough milk.⁴ Additionally, the World Health Organization (WHO) indicates that human donor breast milk can prevent some digestive disorders but specifies that any donor milk must come from safe facilities and is not recommended for sick infants or those weighing less than 1,000 grams.^{5, 6} In the absence of mother's milk, the WHO notes that standard formula is also an acceptable alternative.⁷

Currently, the federal Food and Drug Administration (FDA) considers human donor breast milk a "food" source rather than a medical product. The FDA has not established guidelines or standards for human donor breast milk or milk banks, although it does recommend consulting with a health care provider before feeding it to an infant.⁸ Additionally, the FDA recommends that the caregiver only feed an infant milk from a source that has screened its donors and has taken precautions to ensure milk safety, such as a milk bank.⁹

Human donor breast milk banks and processing entities are not licensed or regulated under Florida law.

¹ Centers for Disease Control and Prevention, *Frequently Asked Questions* (FAQ) (Aug. 10, 2021) available at <https://www.cdc.gov/breastfeeding/faq/i/index.htm> (last visited Jan. 22, 2022).

² *Id.*

³ *Id.*

⁴ American Academy of Pediatrics Committee on Nutrition, Section on Breastfeeding and Committee on Fetus and Newborn, Policy Statement, *Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States* (Jan. 2017) available at <https://publications.aap.org/pediatrics/article/139/1/e20163440/52000/Donor-Human-Milk-for-the-High-Risk-Infant> (last visited Jan. 22, 2022).

⁵ Agency for Health Care Administration, *Agency Analysis of House Bill 1333* (Jan. 12, 2022) (on file with House Finance & Facilities Subcommittee).

⁶ World Health Organization, *Recommendations for the Feeding of low-birth-weight infants in low- and middle-income countries*, available at https://www.who.int/elena/titles/full_recommendations/feeding_lb/en/ (last visited Jan. 22, 2022).

⁷ *Id.*

⁸ U.S. Food and Drug Administration, *Use of Donor Human Milk* (Mar. 22, 2018) available at <https://www.fda.gov/science-research/pediatrics/use-donor-human-milk> (last visited Jan. 22, 2022).

⁹ *Id.*

Human Milk Banking Accreditation and Guidelines

The Human Milk Banking Association of North America (HMBANA) is an accrediting organization for nonprofit milk banks in the United States and Canada.¹⁰ The HMBANA is funded by membership fees from its 31 member nonprofit milk banks, foundation funds, and individual donors.¹¹ There is one HMBANA-accredited location in Florida – the Mother’s Milk Bank of Florida located in Orlando.¹² The Mother’s Milk Bank of Florida supplies pasteurized donor human milk to 38 of the 68 neonatal intensive care units (NICUs) in Florida, as well as to medically fragile babies at home.¹³ A survey by the Agency for Health Care Administration found that Mother’s Milk Bank of Florida supplied 81 percent of the donated human milk used in Florida NICUs responding to the survey.¹⁴

According to the HMBANA, its member milk banks follow guidelines developed in consultation with the CDC and the FDA,¹⁵ however, the FDA says that it has not been involved in establishing any voluntary guidelines.¹⁶

Under the HMBANA’s guidelines, before milk is collected, each donor is strictly screened for medical and lifestyle risk factors and serum is screened for HIV, Human T-lymphotropic virus, syphilis, and Hepatitis B and C.¹⁷ After the milk is collected, it is mixed and pooled so that each pool includes human milk from three to five donors. This is done to ensure an even distribution of nutritional components. Bottles are filled with the pooled milk and then the milk is pasteurized to eliminate potentially harmful bacteria while retaining the majority of the milk’s beneficial nutrients.

Milk samples are taken during the pasteurization process and cultured to check for bacterial growth. Any contaminated milk is discarded. No milk is dispensed after pasteurization until a culture is found to be negative for bacteriological growth. After pasteurization, the milk is frozen and shipped to hospitals and outpatient families.

AHCA Report on Donor Human Milk

In 2021, the Florida Legislature required AHCA, in consultation with the Department of Health (DOH), to study and report on the use of donor human milk as a supplement to newborn care and health specific to newborn infants born prematurely and hospitalized within the NICU.^{18, 19} AHCA published the report on November 1, 2021. It includes best practices recommendations for the oversight of milk banks and their staff, operating procedures, standards for donor screening, and recommendations for the collection, storage, handling, processing, and dispensing of donor human milk. The report also addresses the need for high-quality clinical studies to quantify the efficacy and cost-effectiveness of donor human milk derivatives.²⁰

¹⁰ Human Milk Banking Association of North America, *About Us*, available at <https://www.hmbana.org/about-us/> (last visited Jan. 22, 2022).

¹¹ *Id.*

¹² Human Milk Banking Association of North America, *Find a Milk Bank*, available at <https://www.hmbana.org/find-a-milk-bank/> (last visited Jan. 22, 2022).

¹³ Mothers’ Milk Bank of Florida, *Covid-19 Update*, available at <https://milkbankofflorida.org/covid-19-update/> (last visited Jan. 22, 2022).

¹⁴ Agency for Health Care Administration, Donor Human Milk Legislative Report (Nov. 1, 2021), pp. 10-11, (on file with House Finance & Facilities Subcommittee).

¹⁵ Human Milk Banking Association of North America, *Milk Processing and Safety*, available at <https://www.hmbana.org/our-work/milk-processing-safety.html> (last visited Jan. 22, 2022).

¹⁶ *Supra* note 8.

¹⁷ Human Milk Banking Association of North America, *Milk Banking and COVID-19* (Apr. 2, 2020) available at https://www.hmbana.org/file_download/inline/a04ca2a1-b32a-4c2e-9375-44b37270cfbd (last visited Jan. 22, 2022).

¹⁸ Agency for Health Care Administration, Donor Human Milk Legislative Report (Nov. 1, 2021) (on file with House Finance & Facilities Subcommittee).

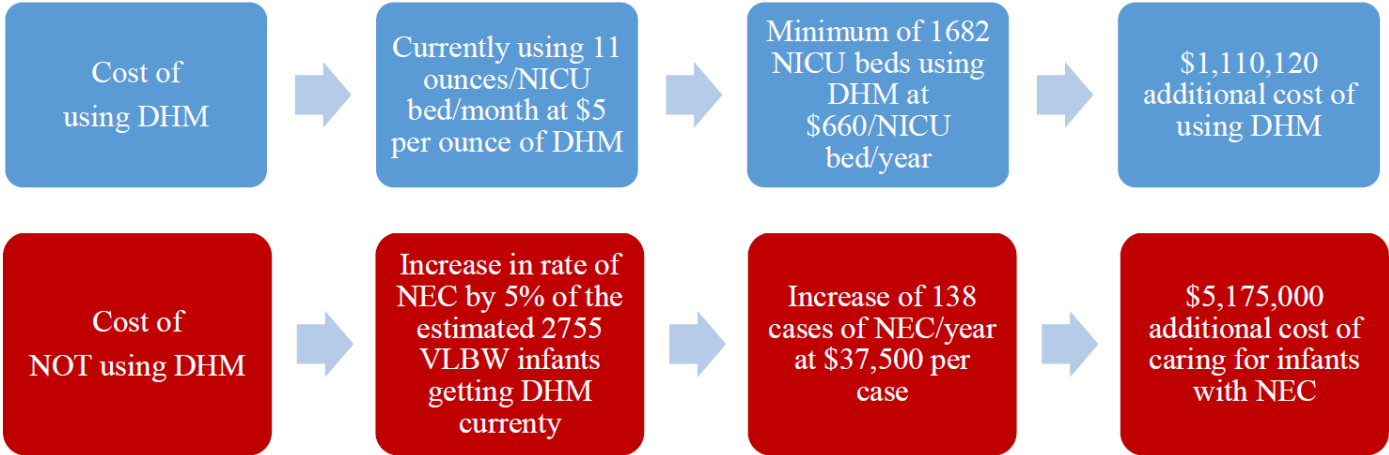
¹⁹ Chapter 2021-36, s. 3, Laws of Fla.

²⁰ *Supra* note 14 at 35.

The report found that about 3,500 infants a year are born in Florida with a very low birth weight (VLBW) - under 1,500 grams or about 3.3 pounds. These infants are at greater risk for a variety of infections and adverse health conditions, including necrotizing enterocolitis (NEC), many of which lead to long-term health problems. AHCA found that premature infants with health complications disproportionately account for a large percentage of health care costs; costing four to seven times as much as premature infants who do not suffer health complications. Much of this cost was driven by premature infants suffering from NEC. U.S. rates of NEC in premature infants range from five percent to 10 percent with increased mortality ranging from 16 percent to 42 percent. AHCA noted that feeding infants human milk, whether it be their mother's own milk or pasteurized donor human milk, is one of the few evidence-based strategies for avoiding NEC.

AHCA found that processing and distribution of donor human milk has increased over seven-fold since 2006 when less than one million ounces were distributed annually in the U.S. compared to 2020 and 2021 when more than seven million ounces were distributed each of those years. AHCA determined that 86 percent of Florida NICUs feed pasteurized donor human milk to their patients. Most of the ones that did not were not the highest level of NICU and did not receive/treat infants under 1,000 grams in weight. The one high level NICU (and two other lower level NICUs) that did not feed infants pasteurized donor human milk reported that cost was a factor in that decision.

AHCA also conducted an economic analysis on the impact of inpatient feeding of pasteurized donor human milk. It found that on \$1.1 million in spending for pasteurized donor human milk, \$5.2 million in avoided additional treatment costs attributable to assumed increases in NEC cases resulted. The following illustrates AHCA's economic analysis.



Florida Medicaid Program

The Medicaid program is a joint federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults and persons with disabilities.²¹ The Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) is responsible for administering the federal Medicaid program. Florida Medicaid is the health care safety net for low-income Floridians. Florida's program is administered by AHCA and financed through state and federal funds.²²

In order to participate in Medicaid, federal law requires states to cover certain population groups and benefits and gives states the flexibility to cover other groups and benefits. States can add "optional"

²¹ Medicaid.gov, *Medicaid*, available at <https://www.medicaid.gov/medicaid/index.html> (last visited Jan. 22, 2022).

²² Section 20.42, F.S.

benefits, such as prescription drugs, adult dental services, and dialysis, with federal approval. AHCA may seek CMS approval for program changes through an amendment to the state plan or waiver.²³

Medicaid enrollees generally receive benefits through one of two service-delivery systems: fee-for-service (FFS) or managed care. Under FFS, health care providers are paid by the state Medicaid program for each service provided to a Medicaid enrollee. Under managed care, AHCA contracts with private managed care plans for the coordination and payment of services for Medicaid enrollees. The state pays the managed care plans a capitation payment, or fixed monthly payment, per recipient enrolled in the managed care plan. Approximately 78 percent of Florida Medicaid recipients receive their benefits in the managed care model.

Medicaid Medical Necessity

Florida Medicaid covers services that are medically necessary, as defined in its Medicaid state plan. AHCA routinely reviews new health services, products, and supplies to assess potential coverage under Florida Medicaid which depends on whether that service, product, or supply is medically necessary.²⁴ Care, goods, and services are medically necessary if they are:

- Necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
- Consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
- Reflective of the level of service that can be safely furnished, and *for which no equally effective and more conservative or less costly treatment is available statewide*; and
- Furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.²⁵

Under federal law, Medicaid states must pay for non-covered services that are medically necessary for recipients under the age of 21.²⁶ This is often referred to as the federal Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) guidelines. Health plans participating in Medicaid managed care must also adhere to EPSDT guidelines.²⁷

Coverage of Nutritional Supplements for Infants in Florida²⁸

Most private insurers do not cover donor human breast milk, which costs approximately \$5 an ounce and can add up to over \$1,000 per month per infant.²⁹

WIC

The Women, Infants, and Children (WIC) program is a federally funded program that provides nutritional support for women and children. Administered by the DOH, WIC provides food assistance

²³ Medicaid.gov, *Medicaid State Plan Amendments*, available at <https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html> (last visited Jan. 22, 2022).

²⁴ *Supra* note 5.

²⁴ *Supra* note 6.

²⁵ Rule 59G-1.010, Florida Administrative Code.

²⁶ 42 C.F.R. s. 441 Subpart B.

²⁷ *Id.*

²⁸ *Supra* note 5.

²⁸ *Supra* note 6.

²⁹ Agency for Health Care Administration, Donor Human Milk Legislative Report (Nov. 1, 2021) (on file with House Finance & Facilities Subcommittee).

such as milk and infant and toddler formulas. If a child is not able to consume a contract formula,³⁰ WIC can make exceptions and provide non-contract formulas with appropriate medical documentation. Contract formulas currently available through WIC include: Enfamil, Enfagrow, Gerber Good Start Soy 1, and Gerber Good Start Soy 3. WIC does not provide human donor breast milk to program participants.

Medicaid

Florida Medicaid covers medically necessary prescription enteral and parenteral commercial formulas under the durable medical equipment and supplies benefit. Commercial formula would be considered medically necessary for infants diagnosed with conditions such as metabolic disorders or who are unable to accept nutrition orally. Medicaid also covers medically necessary commercial formula during an inpatient hospital stay, as part of the all-inclusive payment to the hospital (just as needed food or medicine would be covered for a patient of any age).

Florida Medicaid does not reimburse separately for human donor breast milk or contract formulas covered through WIC. If an infant needed human donor breast milk outside of the hospital setting, a request would need to be made through the EPSDT coverage process. AHCA reports that it is not aware of any such requests being made for infants in fee-for-service or Medicaid managed care.³¹

Medicaid Coverage of Human Donor Breast Milk in Other States³²

STATE	COVERAGE DESCRIPTION
California	Coverage when mother's own milk is insufficient, or infant cannot breastfeed, or contraindication to formula. Cover for inpatient and outpatient.
Iowa	Coverage for infants in the inpatient setting.
Missouri	Coverage for infants under 3 months of age who are critically ill and have medical necessity for human milk diet. Coverage for NICU only.
New York	Coverage for infants with birth weights less than 1,500 grams, infant unable to breastfeed, mother unable to produce sufficient milk, or medical necessity. Coverage for inpatient. Prior authorization required.
Texas	Coverage for inpatient infants at or under six months of age with medical necessity. Coverage for outpatient infants at or under 11 months of age but may be extended through 20 years with inability to tolerate formula and medical necessity. Prior authorization for outpatient. Subsequent reauthorization for both inpatient and outpatient.
Kansas	Coverage for infants under 3 months of age who are critically ill and have medical necessity. Coverage for NICU only. Prior authorization required.
New Jersey	Coverage for infants under 6 months of age, infant unable to breastfeed, mother unable to produce sufficient milk, infant body weight below healthy level, or medically necessary. Coverage for inpatient and outpatient.
Utah	Coverage for infants under 11 months of age with medical necessity. Cover for outpatient only. Prior authorization with reauthorization.

³⁰ Commercial infant formula manufacturers provide substantial discounts, in the form of rebates, to state WIC programs in return for the exclusive right to provide their products to the state's WIC participants. Commercial formulas whose manufacturers have those exclusive rights are considered "contract formulas." See Steven Carlson, Robert Greenstein, and Zoe Neuberger, Center on Budget and Policy Priorities, *WIC's Competitive Bidding Process for Infant Formula Is Highly Cost-Effective* (Feb. 17, 2017) available at <https://www.cbpp.org/sites/default/files/atoms/files/6-26-15fa.pdf> (last viewed Mar. 4, 2021).

³¹ *Supra* note 5.

³² *Supra* note 5.

³² *Supra* note 6.

STATE	COVERAGE DESCRIPTION
District of Columbia	Coverage of infants under 11 months of age who are unable to tolerate formula and have medical necessity. Coverage for inpatient and outpatient. Prior authorization and reauthorization required.
Connecticut	Coverage when medically necessary, infant unable to breastfeed, or mother unable to produce insufficient milk.

Effect of the Bill

The bill requires Medicaid coverage of donor human milk in Medicaid managed care and fee for service programs for inpatient hospital infant care. The donor human milk must be prescribed by a licensed physician, physician assistant, nurse practitioner, or dietician.

To be eligible, the infant's mother must be medically or physically unable to produce breastmilk or breastfeed; the infant must be medically unable to receive maternal milk or breast feed, or physically unable to receive maternal milk or breastfeed. In addition, the infant must have a documented birth weight of 1,800 grams or less, and:

- Have a congenital or acquired condition and be at high risk of developing a feeding intolerance, necrotizing enterocolitis, or an infection; or
- Otherwise have a medical indication for human milk diet.

The bill requires AHCA to establish provider eligibility, by rule, and authorizes AHCA to seek any necessary federal approvals for the new Medicaid benefit.

The bill is effective July 1, 2022.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The 2021 AHCA report estimated the cost of coverage of human donor milk and derivatives for inpatient treatment, based on current utilization. The report estimated a cost \$1,110,120 per year for all eligible infants in Florida, assuming an annual cost of \$660 per NICU bed and assuming 1,682 NICU beds in Florida. Assuming 58 percent of childbirths are covered by the Medicaid program, the annual total cost to the program for such inpatient coverage would be \$643,869.³³

The fiscal impact to the Medicaid Program is insignificant and would likely not result in a material impact to Medicaid Hospital Inpatient fee for service rates or Medicaid Medical Managed Assistance per member per month rates.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

³³ *Supra*, note 19 (but assuming 11 oz. per NICU bed per month, as reported by Florida NICUs).

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Non-profit milk banks meeting the provider eligibility criteria established by AHCA under the bill may experience increased demand for donor human milk from Medicaid enrollees.

Eligible milk banks will have to post a \$50,000 surety bond to enroll as a Durable Medical Equipment and Supplies provider to participate in Florida Medicaid, pursuant to current law for such Medicaid providers.³⁴

D. FISCAL COMMENTS:

None.

³⁴ S. 409.912, F.S.