

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: SB 1770

INTRODUCER: Senator Book

SUBJECT: Donor Human Milk Bank Services

DATE: January 25, 2022

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Smith</u>	<u>Brown</u>	<u>HP</u>	<u>Favorable</u>
2.	_____	_____	<u>AHS</u>	_____
3.	_____	_____	<u>AP</u>	_____

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**I. Summary:**

SB 1770 authorizes Florida Medicaid to pay for donor human milk bank services as an optional covered service in the fee-for service delivery system and requires health plans participating in the Statewide Medicaid Managed Care program to cover donor human milk bank services. The bill specifies health conditions for which human donor milk services would be medically necessary and provides requirements that milk banks must meet in order to qualify as Medicaid providers. The bill establishes that Medicaid's reimbursement rates for donor human milk cannot be less than the milk bank's cost to procure it plus reasonable processing and handling fees.

Because human donor milk is not currently a covered service, the bill will have an indeterminate negative fiscal impact on Florida Medicaid. *See* Section V of this analysis.

The bill provides an effective date of July 1, 2022.

**II. Present Situation:**

**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.<sup>1</sup> 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.<sup>2</sup> 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

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

<sup>2</sup> *Id.*

of having their premature infant in intensive care.<sup>3</sup> 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.<sup>4</sup>

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.<sup>5</sup> 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 1000 grams.<sup>6, 7</sup> In the absence of a mother's milk, the WHO notes that standard formula is also an acceptable alternative.<sup>8</sup>

Currently, the federal Food and Drug Administration (FDA) considers human donor breast milk a "food" source rather than a medical product. The FDA does not have 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.<sup>9</sup> 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.<sup>10</sup>

### ***The Human Milk Banking Association of North America (HMBANA)***

Founded in 1985, the Human Milk Banking Association of North America (HMBANA) serves as the professional organization that accredits nonprofit milk banks in the United States and Canada.<sup>11</sup> The HMBANA is funded by membership fees from its 31 member nonprofit milk banks, foundation funds, and individual donors.<sup>12</sup> There is one HMBANA-accredited location in Florida – the Mother's Milk Bank of Florida located in Orlando.<sup>13</sup> The Mother's Milk Bank of

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<sup>3</sup> Naseem S. Miller, *Bill aims to get Medicaid coverage for donor breast milk: 'Something like this makes smart policy'*, Orlando Sentinel (Mar. 15, 2019) available at <https://www.orlandosentinel.com/health/os-ne-mothers-milk-bank-bill-20190315-story.html> (last visited Jan. 22, 2022).

<sup>4</sup> *Supra* note 1.

<sup>5</sup> 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).

<sup>6</sup> Agency for Health Care Administration, *Senate Bill 240 Fiscal Analysis* (Dec. 28, 2020) (on file with Senate Committee on Health Policy).

<sup>7</sup> 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/](https://www.who.int/elena/titles/full_recommendations/feeding_lb/en/) (last visited Jan. 22, 2022).

<sup>8</sup> *Id.*

<sup>9</sup> 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).

<sup>10</sup> *Id.*

<sup>11</sup> Human Milk Banking Association of North America, *About Us*, available at <https://www.hmbana.org/about-us/> (last visited Jan. 22, 2022).

<sup>12</sup> *Id.*

<sup>13</sup> 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).

Florida supplies pasteurized donor human milk to 38 of the 68<sup>14</sup> neonatal intensive care units (NICUs) in Florida, as well as to medically fragile babies at home.<sup>15</sup>

### ***HMBANA Safety Guidelines***<sup>16</sup>

The HMBANA reports that its member milk banks follow guidelines that were developed by the HMBANA in consultation with the CDC and the FDA. The FDA reports that it has not been involved in establishing these voluntary guidelines.<sup>17</sup> According to the AHCA, no federal or state regulations are in place to oversee the Mother's Milk Bank of Florida.<sup>18</sup>

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, HTLV, syphilis, and Hepatitis B and C.<sup>19</sup> 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**<sup>20</sup>

In 2021, the Florida Legislature passed the General Appropriations Act, SB 2500, which required the 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.<sup>21</sup> On November 1, 2021, the report was published. It includes recommendations of best practices 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.<sup>22</sup>

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<sup>14</sup> *Supra* note 3.

<sup>15</sup> Mothers' Milk Bank of Florida, *Covid-19 Update*, available at <https://milkbankofflorida.org/covid-19-update/> (last visited Jan. 22, 2022).

<sup>16</sup> 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).

<sup>17</sup> *Supra* note 9.

<sup>18</sup> *Supra* note 6.

<sup>19</sup> 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](https://www.hmbana.org/file_download/inline/a04ca2a1-b32a-4c2e-9375-44b37270cfbd) (last visited Jan. 22, 2022).

<sup>20</sup> Agency for Health Care Administration, *Donor Human Milk Legislative Report* (Nov. 1, 2021) (on file with Senate Committee on Health Policy).

<sup>21</sup> Chapter 2021-36, s. 3, Laws of Fla.

<sup>22</sup> *Supra* note 20 at 45.

## 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.<sup>23</sup> 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 the AHCA and financed through state and federal funds.<sup>24</sup>

A Medicaid state plan is an agreement between a state and the federal government describing how the state administers its Medicaid programs. The state plan establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements.

In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives states the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility criteria within federal minimum standards. The AHCA may seek an amendment to the state plan as necessary to comply with federal or state laws or to implement program changes. States send state plan amendments to the federal CMS for review and approval.<sup>25</sup>

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, the 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.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program.<sup>26</sup> The SMMC program has two components, the Managed Medical Assistance (MMA) program and the Long-term Care program. Florida's SMMC offers a health care package covering both acute and long-term care.<sup>27</sup> The SMMC benefits are authorized by federal authority and are specifically required in ss. 409.973 and 409.98, F.S.

The AHCA contracts with managed care plans on a regional basis to provide services to eligible recipients. The MMA program, which covers most medical and acute care services for managed care plan enrollees, was fully implemented in August 2014, and was re-procured for a period beginning December 2018 and ending in 2023.<sup>28</sup>

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<sup>23</sup> Medicaid.gov, *Medicaid*, available at <https://www.medicaid.gov/medicaid/index.html> (last visited Jan. 22, 2022).

<sup>24</sup> Section 20.42, F.S.

<sup>25</sup> Medicaid.gov, *Medicaid State Plan Amendments*, available at <https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html> (last visited Jan. 22, 2022).

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

### ***Medical Necessity Requirements***

Florida Medicaid covers services that are medically necessary, as defined in its Medicaid state plan pursuant to Rule 59G-1.010 of the Florida Administrative Code. The 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.<sup>29</sup> Pursuant to Rule 59G-1.010 of the Florida Administrative Code 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.

Under federal law, Medicaid states must have a process in place to pay for services that are medically necessary but are not covered for recipients under the age of 21.<sup>30</sup> This is often referred to as the federal Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) guidelines. Health plans participating in the SMMC program must also adhere to EPSDT guidelines.<sup>31</sup>

### **Coverage of Nutritional Supplements for Infants in Florida<sup>32</sup>**

Florida Medicaid covers prescription enteral and parenteral commercial formulas under the Durable Medical Equipment and Supplies benefit, when medically necessary. Commercial formula would be considered medically necessary for infants diagnosed with conditions such as metabolic disorders or who are unable to accept nutrition orally. In addition, if an infant needs commercial formula during an inpatient hospital stay, it would be covered 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.

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 such as milk and infant and toddler formulas. If a child is not able to consume a contract formula,<sup>33</sup> WIC can make exceptions and provide non-contract formulas with

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<sup>29</sup> *Supra* note 6.

<sup>30</sup> 42 C.F.R. s. 441 Subpart B.

<sup>31</sup> *Id.*

<sup>32</sup> *Supra* note 6.

<sup>33</sup> 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*

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.

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.<sup>34</sup>

Most private insurers do not cover donor human breast milk, which costs approximately \$4 an ounce and can add up to over \$1,000 per month per infant.<sup>35</sup> Through donations and fundraisers, the Mother's Milk Bank of Florida provides grants to low-income families to make donor human breast milk more affordable.<sup>36</sup>

### Medicaid Coverage of Human Donor Breast Milk in Other States

At least seven states (California, Connecticut,<sup>37</sup> New York<sup>38</sup>, Missouri, Kansas, Texas, and Utah) and the District of Columbia provide coverage for human donor breast milk under their state Medicaid programs.<sup>39</sup> In July 2017, New York Medicaid began covering pasteurized human donor breast milk, in both its fee-for-service and managed care delivery systems, but only during the infant's inpatient hospital stay.<sup>40</sup> California Medicaid has been covering human donor breast milk since 1998, but only covers it when the mother is unable to utilize her own milk supply and the infant cannot tolerate or has medical contraindications to the use of any formula, including enteral formula.<sup>41</sup>

### III. Effect of Proposed Changes:

**Section 1** of the bill amends s. 409.906, F.S., to authorize the AHCA to reimburse through Florida Medicaid for the cost of donor human milk for home and inpatient use for an infant who:

- Is medically or physically unable to receive maternal breast milk or whose mother medically or physically unable to produce maternal breast milk or breastfeed; and

*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).

<sup>34</sup> *Supra* note 6.

<sup>35</sup> *Supra* note 3.

<sup>36</sup> *Id.*

<sup>37</sup> Naomi Bar-Yam, Ph.D., Mother's Milk Bank Northeast, *Medicaid Coverage of Donor Milk Now Law in Connecticut* (July 23, 2019) available at <https://milkbankne.org/2019/07/medicaid-coverage-of-donor-milk-now-law-in-connecticut/> (last visited Jan. 22, 2022).

<sup>38</sup> Anna Berry, Nonprofit Quarterly, *Liquid Gold: 6 States Allow Medicaid Access for Breast Milk* (Apr. 2017) available at <https://nonprofitquarterly.org/liquid-gold-6-states-allow-medicaid-access-breast-milk/> (last visited Jan. 22, 2022).

<sup>39</sup> Center for Evidence-based Policy, Oregon Health & Science University, *Donor Human Milk for Low-Birthweight Infants: Effectiveness and Policies* (Apr. 2017) at 22 available at [https://www.health.ny.gov/health\\_care/medicaid/ebprac/docs/2017-06-13\\_donor\\_human\\_milk.pdf](https://www.health.ny.gov/health_care/medicaid/ebprac/docs/2017-06-13_donor_human_milk.pdf) (last visited Jan. 22, 2022).

<sup>40</sup> New York State Department of Health, Medicaid Update, *NYS Medicaid Coverage of Pasteurized Donor Human Milk* (July 2017) available at [https://www.health.ny.gov/health\\_care/medicaid/program/update/2017/2017-07.htm](https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-07.htm) (last visited Jan. 22, 2022).

<sup>41</sup> *Supra* note 6.

- Has a documented birth weight of 1,500 grams or less; has a congenital or acquired intestinal condition and is at high risk for developing a feeding intolerance, necrotizing enterocolitis, or an infection; or otherwise requires nourishment by breast milk.

Because a service covered under Florida Medicaid is only considered to be medically necessary if no equally effective and more conservative or less costly treatment is available, a provider seeking to be reimbursed under the Medicaid program would need to demonstrate that the infant cannot tolerate or has medical contra-indications for commercial formula (available through programs like WIC or prescription formulas already covered under Medicaid) to the extent that these options are more cost effective.

The bill requires the donor human milk to be procured from a nonprofit milk bank certified by the Human Milk Banking Association of North America (HMBANA). For a milk bank to procure donor human milk, it would need to enroll as a Durable Medical Equipment provider under Florida Medicaid and to comply with provider requirements such as providing a surety bond of \$50,000 pursuant to s. 409.912(8)(b), F.S.

The bill specifies that coverage for donor human milk may not be for less than the reasonable cost of the milk procured from a HMBANA-certified milk bank, plus reasonable processing and handling fees.

**Section 2** of the bill amends s. 409.908, F.S., to authorize Florida Medicaid to pay for donor human milk bank services as an optional covered service in the fee-for service delivery system.

**Section 3** of the bill amends s. 409.973, F.S., to require health plans participating in the Statewide Medicaid Managed Care (SMMC) program to cover donor human milk bank services.

**Section 4** of the bill provides an effective date of July 1, 2022.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

In order to be reimbursed for donor human milk provided to infants enrolled in SMMC plans, milk banks would need to contract with the plans.

C. Government Sector Impact<sup>42</sup>:

Because human donor milk is not currently a covered service, the bill will have indeterminate negative fiscal impact on Florida Medicaid. It is unknown how many infants would satisfy the health conditions specified in the bill and meet Medicaid's medical necessity criteria. Therefore, the AHCA's projected fiscal impact focuses on a percentage of infants with a very low birth weight of 1,500 grams or less in a NICU.

In 2021, the AHCA provided a fiscal estimate for SB 240 which was at the time, identical to this bill with an effective date of July 1, 2021. In the 2019-2020 fiscal year, there were 2,494 infants with a very low birth weight of 1,500 grams or less in a NICU covered by Medicaid. AHCA's analysis assumes that 47.60 percent of these infants will receive donor milk for the first six months of life. (These infants may be eligible to receive donor milk for up to 12 months.) The 47.60 percent figure is based on the count for breastfed babies in Florida who are not breastfeeding at six months according to information from the CDC. Based on those assumptions, the AHCA's estimated cost to the Medicaid program in the 2022-2023 fiscal year was \$29,867,890 with \$11,657,438 being the state share.

The changes in this bill would require the AHCA to update its rules, fee schedules, and contracts with the SMMC health plans. These actions are part of the AHCA's routine business practices and ACHA reports that this can be accomplished using existing resources.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

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<sup>42</sup> *Supra* note 6.



**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 409.906, 409.908, and 409.973.

**IX. Additional Information:**

**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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