

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.)

Prepared By: The Professional Staff of the Committee on Appropriations

BILL: CS/SB 1770

INTRODUCER: Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services) and Senators Book and Stewart

SUBJECT: Donor Human Milk Bank Services

DATE: February 25, 2022

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Smith</u>	<u>Brown</u>	<u>HP</u>	Favorable
2.	<u>McKnight</u>	<u>Money</u>	<u>AHS</u>	Recommend: Fav/CS
3.	<u>McKnight</u>	<u>Sadberry</u>	<u>AP</u>	Fav/CS

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1770 authorizes the Florida Medicaid program to reimburse 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 is medically or physically unable to produce maternal breast milk or breastfeed, and who also meet specified eligibility factors. The bill also requires the Agency for Health Care Administration (AHCA) to establish provider eligibility, by rule, and authorizes the AHCA to seek any necessary federal approvals to implement the new coverage benefit.

The bill has a significant negative fiscal impact to the Florida Medicaid program. *See* Section V of this analysis.

The bill takes effect on 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.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 are not ready, they too are sick, or they are affected by the stress of having their premature infant in intensive care.³ 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.⁴

The American Academy of Pediatrics 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.⁵ 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.^{6, 7} In the absence of a mother's milk, the WHO notes that standard formula is also an acceptable alternative.⁸

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.⁹ 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.¹⁰

¹ 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).

² *Id.*

³ 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).

⁴ 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).

⁵ 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).

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

⁷ 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).

⁸ *Id.*

⁹ 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).

¹⁰ *Id.*

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.¹¹ The HMBANA is funded by membership fees from its 31 member nonprofit milk banks, foundation funds, and individual donors.¹² There is one HMBANA-accredited location in Florida – the Mother’s Milk Bank of Florida located in Orlando.¹³ The Mother’s Milk Bank of Florida supplies pasteurized donor human milk to 38 of the 68¹⁴ neonatal intensive care units (NICUs) in Florida, as well as to medically fragile babies at home.¹⁵

HMBANA Safety Guidelines¹⁶

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.¹⁷ According to the AHCA, no federal or state regulations are in place to oversee the Mother’s Milk Bank of Florida.¹⁸

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.¹⁹ 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.

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

¹² *Id.*

¹³ *Id.*

¹⁴ 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).

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

¹⁶ 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).

¹⁷ 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).

¹⁸ Agency for Health Care Administration, *Senate Bill 240 Fiscal Analysis* (Dec. 28, 2020) (on file with Senate Committee on Health Policy).

¹⁹ 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).

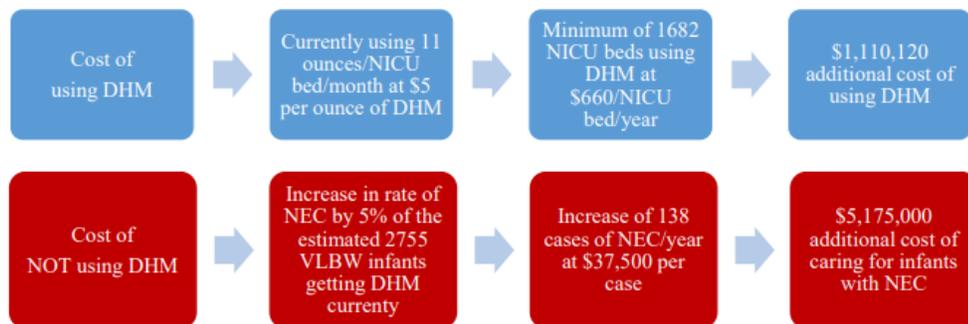
AHCA Report on Donor Human Milk²⁰

In 2021, the Legislature required the Agency for Health Care Administration (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.²¹ On November 1, 2021, the report was published. The study reports that a survey of Florida NICUs in 2021 determined that 86 percent of them use pasteurized donor human milk (PDHM). The most common reasons for administering PDHM were prematurity (92 percent), birth weight threshold (76 percent), and medical necessity (71 percent) determined by the attending physician based on diagnosis and symptoms.

The report 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. In addition, the report addresses the need for high-quality clinical studies to quantify the efficacy and cost-effectiveness of donor human milk derivatives.

The AHCA report also conducted an economic analysis on the impact of inpatient feeding of PDHM. While PDHM use is not currently reimbursable by the Florida Medicaid program or commercial health insurance companies, some Florida hospitals have earned grant funding or donations to support the provision of PDHM, and most large facilities using PDHM have chosen to do so knowing that the cost will not be reimbursed. These facilities balance the direct costs of PDHM use with better outcomes, in hopes that improved outcomes will ultimately decrease total cost of care by reducing risk and severity of necrotizing enterocolitis (NEC), a severe and lethal complication affecting premature and low birth weight infants, and other illnesses associated with prematurity.

In Florida, approximately 3,500 infants are born with a very low birth weight (VLBW) (birth weight less than 1,500 grams or 3.5 pounds) annually. The AHCA report found that if Florida NICUs were to stop using PDHM, there would be a 5 percent increase in the number NEC cases from the 2,755 VLBW infants born annually in Florida. As illustrated in the chart below, when comparing costs of providing PDHM (\$1.1 million) to estimated costs of not using PDHM (\$5.2 million), there is an estimated \$4.1 million cost avoidance statewide among all payers.



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

²¹ Chapter 2021-36, s. 3, Laws of Fla.

The report finds that the avoided cost is largely predicated on the management of NEC. This cost-avoidance is among all payers; however, it is particularly relevant to the Florida Medicaid program given its coverage of over 50 percent of births in the State of Florida. Furthermore, the report states that this cost-avoidance with PDHM is an underestimate, as it does not factor in additional benefits after the birth hospitalization with respect to readmissions, home nursing, and emergency room visits.

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.²² 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.²³

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.²⁴

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.²⁵ 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

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

²³ Section 20.42, F.S.

²⁴ Medicaid.gov, *Medicaid State Plan Amendments*, available at <https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html> (last visited Jan. 22, 2022).

²⁵ *Id.*

covering both acute and long-term care.²⁶ 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 2023.²⁷ In 2020, the Legislature extended the allowable term of the SMMC contracts from five to six years.²⁸ As a result, the AHCA's current contracts will end in December 2024.

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.²⁹

Care, goods, and services are deemed 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.³⁰

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 21.³¹ 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.³²

Coverage of Nutritional Supplements for Infants in Florida³³

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

²⁶ *Id.*

²⁷ *Id.*

²⁸ Chapter 2020-156, s. 44, Laws of Fla.

²⁹ Agency for Health Care Administration, *Senate Bill 240 Fiscal Analysis* (Dec. 28, 2020) (on file with Senate Committee on Health Policy).

³⁰ 59G-1.010, F.A.C.

³¹ 42 C.F.R. s. 441 Subpart B.

³² *Id.*

³³ *Supra* note 30.

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,³⁴ 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.

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. The AHCA reports that it is not aware of any such requests being made for infants in fee-for-service or Medicaid managed care.³⁵

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.³⁶ 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.³⁷

Medicaid Coverage of Human Donor Breast Milk in Other States

Currently nine states (California, Connecticut, Iowa, Kansas, Missouri, New Jersey, New York, Texas, and Utah) and the District of Columbia, provide coverage for human donor milk under their state Medicaid programs.³⁸

³⁴ 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).

³⁵ Agency for Health Care Administration, *Senate Bill 240 Fiscal Analysis* (Dec. 28, 2020) (on file with Senate Committee on Health Policy).

³⁶ 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).

³⁷ *Id.*

³⁸ Agency for Health Care Administration, *Donor Human Milk Legislative Report* (Nov. 1, 2021) (on file with Senate Committee on Health Policy).

State Medicaid Coverage Policies for Donor Human Milk³⁹		
State/Territory	Description of Coverage	HMBANA Bank in State
California	Coverage when mother's own milk is insufficient, or infant cannot breastfeed, or contraindication to formula. Cover for inpatient and outpatient.	Yes
Connecticut	Coverage when medically necessary, infant unable to breastfeed, or mother unable to produce insufficient milk.	No
Iowa	Coverage for infants in the inpatient setting.	Yes
Kansas	Coverage for infants under 3 months of age who are critically ill and have medical necessity. Coverage for NICU only. Prior authorization required.	No
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.	Yes
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.	No
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.	Yes
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.	Yes
Utah	Coverage for infants under 11 months of age with medical necessity. Cover for outpatient only. Prior authorization with reauthorization.	Yes
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.	No

³⁹ *Id.*

III. Effect of Proposed Changes:

Section 1 amends s. 409.906, F.S., to authorize the Agency for Health Care Administration (AHCA) to reimburse through Florida Medicaid for the cost of donor human milk for inpatient use as ordered by a licensed physician, nurse practitioner, physician assistant, 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 breast milk or breastfeed, 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 for developing a feeding intolerance, necrotizing enterocolitis, or an infection; or
- Otherwise have a medical indication for a human milk diet.

Section 2 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 amends s. 409.973, F.S., to require health plans participating in the Statewide Medicaid Managed Care program to cover donor human milk bank services.

Section 4 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:

None.

C. Government Sector Impact⁴⁰:

Because human donor milk is not currently a covered service, CS/SB 1770 would have a significant negative fiscal impact on the Florida Medicaid program. Based on data provided by the Agency for Health Care Administration (AHCA), the maximum estimated cost to the Florida Medicaid program in Fiscal Year 2022-2023 is a recurring \$4.1 million, of which \$1.6 million is general revenue.

The AHCA’s estimate assumes 50 percent of infants with birth weights of 1,999 grams or less are eligible for Florida Medicaid, even though the bill would only reimburse for infants weighing 1,800 grams or less. The AHCA utilizes diagnosis codes for birth weights of up to 1,749 grams and up to 1,999 grams; there is no code tied to a birth weight of 1,800 grams. Therefore, the AHCA used the code associated with 1,999 grams to ensure infants weighing 1,800 grams or less are included in the estimate.

	Infants Eligible for Donor Milk	Estimated Total Fiscal Impact	General Revenue	Trust Fund
Infants born <1500g	843	\$ 2,758,806	\$ 1,095,246	\$ 1,663,560
Infants born 1500g-1999g	1009	\$ 1,300,690	\$ 516,374	\$ 784,316
Total	1852	\$ 4,059,496	\$ 1,611,620	\$ 2,447,876

It is unknown how many infants would satisfy the health conditions specified in the bill and meet Medicaid’s medical necessity criteria. However, taking into consideration the cost comparison of providing donor human milk to estimated costs of not using donor human as reported in the AHCA’s Donor Human Milk Legislative Report to the Florida Legislature and highlighted in Section 2 of this bill analysis, there is a possible cost avoidance statewide among all payers particularly relevant to the Florida Medicaid program, given its coverage of over 50 percent of births in the State of Florida. Furthermore, the AHCA report states that this cost-avoidance with donor human milk is an underestimate, as it does not factor in additional benefits after the birth hospitalization with respect to readmissions, home nursing, and emergency room visits. Without additional data on the additional benefits, any potential savings that would offset costs realized from a policy change are indeterminate at this time.

VI. Technical Deficiencies:

None.

⁴⁰ Email from the Agency for Health Care Administration to the Senate Appropriations Subcommittee on Health and Human Services (Feb. 15, 2022) (on file with the Senate Appropriations Subcommittee on Health and Human Services).

VII. Related Issues:

None.

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 Substantial Changes:**

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

CS by Appropriations on February 24, 2022:

The committee substitute:

- Permits the Medicaid program to pay only for inpatient use of donor human milk and products.
- Adds physician assistants and dieticians to the list of approved health care providers who may order such products for payment by Medicaid.
- Increases the infant maximum documented birth weight from 1,500 grams or less, to 1,800 grams or less, for eligibility for payment of donor human or donor human milk products.
- Removes the requirement that donor human milk or donor human milk products be obtained from a nonprofit milk bank certified by the Human Milk Banking Association of North America.
- Removes the cost reimbursement floor for donor human milk or donor human milk products.
- Requires the Agency for Health Care Administration (AHCA) to establish provider eligibility, by rule, and authorizes the AHCA to seek any necessary federal approvals to implement the new coverage benefit.

B. Amendments:

None.