

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 Health Policy

BILL: CS/SB 240

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Donor Human Milk Bank Services

DATE: March 10, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	Fav/CS
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 240 requires the Department of Health (DOH) to adopt rules and establish minimum standards for the regulation of donor human milk banks which must address the operations of the bank and procedures for donating, distributing, and testing donor human milk and its derivatives. The bill requires a donor human milk bank operating in this state to comply with the DOH standards.

The bill provides an effective date of July 1, 2021.

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 aren't ready, they too are sick, or they're affected by the stress

¹ Centers for Disease Control and Prevention, *Frequently Asked Questions* (FAQ) (May 28, 2020) available at <https://www.cdc.gov/breastfeeding/faq/index.htm> (last visited Mar. 4, 2021).

² *Id.*

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 (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.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

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

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 Mar. 2, 2021).

⁴ *Supra* note 1.

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://pediatrics.aappublications.org/content/pediatrics/139/1/e20163440.full.pdf> (last visited Mar. 4, 2021).

⁶ Agency for Health Care Administration, *Senate Bill 240 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 Mar. 4, 2021).

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 Mar. 2, 2021).

¹⁰ *Id.*

¹¹ Human Milk Banking Association of North America, *About Us*, available at <https://www.hmbana.org/about-us/> (last visited Mar. 2, 2021).

¹² *Id.*

¹³ Human Milk Banking Association of North America, *Find a Milk Bank*, available at <https://www.hmbana.org/find-a-milk-bank/> (last visited Mar. 2, 2021).

¹⁴ *Supra* note 3.

(NICUs) in Florida, as well as to medically fragile babies at home who have been prescribed human donor breast milk.¹⁵

Donor human breast milk, which costs approximately \$4 an ounce and can add up to over \$1,000 per month per infant, is not covered by Florida Medicaid or by most private insurers.¹⁶ 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.¹⁷

*HMBANA Safety Guidelines*¹⁸

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.¹⁹ According to the AHCA, no federal or state regulations are in place to oversee the Mother's Milk Bank of Florida.²⁰

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.²¹ 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.

III. Effect of Proposed Changes:

Section 1 of the bill creates s. 383.017, F.S., relating to donor human milk banks. The bill provides that it is the intent of the Legislature to protect the health, safety, and welfare of human milk donors and recipients of human milk donation and to encourage the use of donor human milk and donor human milk derivatives.

The bill defines a "donor human milk bank" as any entity or organization operating within this state which collects, processes, stores, tests, or distributes donor human milk or donor human milk derivatives.

¹⁵ Mothers' Milk Bank of Florida, *Covid-19 Update*, available at <https://milkbankofflorida.org/covid-19-update/> (last visited Mar. 2, 2021).

¹⁶ *Supra* note 3.

¹⁷ *Id.*

¹⁸ 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 Mar. 2, 2021).

¹⁹ *Supra* note 9.

²⁰ *Supra* note 6.

²¹ 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 Mar. 2, 2021).

The bill requires the DOH to establish minimum standards for the regulation of donor human milk banks which must address:

- The operation of a donor human milk bank that facilitates the donation, processing, and distribution of donor human milk and donor human milk derivatives;
- Procedures for donation and distribution of donor human milk and donor human milk derivatives; and
- Testing of donor human milk and donor human milk derivatives before donation, processing, and distribution to ensure the absence of adulterants and other contaminants as determined by the DOH.

The bill requires a donor human milk bank operating in this state to comply with the DOH standards.

The bill requires the DOH to adopt rules to implement s. 383.017, F.S., as created by the bill.

Section 2 of the bill provides an effective date of July 1, 2021.

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 Impact:

The bill may pose a minor fiscal and operational impact on the DOH as it adopts rules and establishes minimum standards for donor human milk banks. The fiscal impact may be absorbed within existing DOH resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires a donor human milk bank operating in this state to comply with the DOH's minimum standards for donor human milk banks, but the DOH will not license such entities under the bill and is not given authority to enforce compliance.

VIII. Statutes Affected:

This bill creates section 383.017 of the Florida Statutes.

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 Health Policy on March 10, 2021:

The CS replaces the Medicaid reimbursement authorizations and requirements in the underlying bill and instead requires:

- The DOH to adopt rules and establish minimum standards for the regulation of donor human milk banks which must address the operations of the bank and procedures for donating, distributing, and testing donor human milk and its derivatives.
- A donor human milk bank operating in this state to comply with the DOH standards.

- B. **Amendments:**

None.