**South Carolina General Assembly**

124th Session, 2021-2022

**S. 485**

**STATUS INFORMATION**

General Bill

Sponsors: Senator Shealy

Document Path: l:\s-res\ks\015prol.kmm.ks.docx

Companion/Similar bill(s): 3749, 4254

Introduced in the Senate on January 25, 2021

Currently residing in the Senate Committee on **Medical Affairs**

Summary: Human milk products

**HISTORY OF LEGISLATIVE ACTIONS**

Date Body Action Description with journal page number

1/25/2021 Senate Introduced and read first time ([Senate Journal‑page 2](file:///h:\sj\20210125.docx))

1/25/2021 Senate Referred to Committee on **Medical Affairs** ([Senate Journal‑page 2](file:///h:\sj\20210125.docx))

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**VERSIONS OF THIS BILL**

[1/25/2021](file:///p:\pprever\2021-22\485_20210125.docx)

**A** **BILL**

TO AMEND CHAPTER 37, TITLE 44 OF THE 1976 CODE, RELATING TO THE CARE OF THE NEWLY BORN, BY ADDING SECTION 44‑37‑75, TO REQUIRE THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL TO ESTABLISH A PROGRAM TO REGULATE AND LICENSE MILK BANKS THAT COLLECT, DONATE, PROCESS, SELL, OR DISTRIBUTE PASTEURIZED DONOR HUMAN MILK AND HUMAN MILK PRODUCTS; AND TO AMEND SECTION 38‑71‑140, RELATING TO NEWBORN HEALTH INSURANCE COVERAGE REQUIREMENTS, TO REQUIRE COVERAGE OF PASTEURIZED DONOR HUMAN MILK AND HUMAN MILK PRODUCTS FOR CERTAIN NEWBORN CHILDREN.

Whereas, our most fragile newborn babies, such as those born at a very low birthweight, those susceptible to necrotizing enterocolitis and delayed neurological development, or those with other complications, deserve and require the best possible medical care, and neonatologists and pediatricians agree that the standard of care is to deliver optimal nutrition, including high‑quality donor human milk as appropriate; and

Whereas, preterm babies who receive an exclusively human milk diet are less likely to develop necrotizing enterocolitis, a serious intestinal disease that attacks the intestinal track, and other life‑changing illnesses or conditions such as delayed neurological development, obesity, diabetes, and childhood leukemia and lymphoma; and

Whereas, the human milk banking industry has grown significantly in recent years in response to a large and growing body of evidence that suggests that human milk is the best possible nutrition for newborn babies, including from experts at the American Academy of Pediatrics and the Centers for Disease Control and Prevention, who have long agreed that human milk is the optimal food source for newborns, helping provide the right mix of nutrition, bioactive proteins, and human milk oligosaccharides that can help strengthen a newborn’s immune system, helping prevent neonatal complications and disease; and

Whereas, the lack of federal oversight of human milk banks and the products they produce is particularly concerning, given the real and growing threat that unsafe, unregulated donor human milk can pose to babies; and

Whereas, human milk is a biologic/tissue and, like other biologics/tissues, can pose a range of threats due to contamination, including from bacteria, viruses, adulterants, and contaminants. Many of these threats can be mitigated by testing, pasteurization, and other processes, assuming they are conducted properly; and

Whereas, milk banking that follows appropriate screening, testing, processing, and dispensing guidelines offers an alternative for nutritious and safe human milk for premature and ill infants who require donor milk and donor milk‑derived products, which can help prevent disease and shorten hospitalization stays by two weeks, improving outcomes and leading to a significant cost savings. Now, therefore,

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Chapter 37, Title 44 of the 1976 Code is amended by adding:

“Section 44‑37‑75. The Department of Health and Environmental Control shall establish a program to regulate and license all milk banks that collect, donate, process, sell, or distribute pasteurized donor human milk and human milk products derived from pasteurized donor human milk in South Carolina. The Department of Health and Environmental Control shall promulgate regulations to carry out the provisions of this section.”

SECTION 2. A. Section 38‑71‑140 of the 1976 Code is amended by adding an appropriately lettered new subsection at the end to read:

“( ) The coverage for a newly born child shall include coverage for pasteurized donor human milk and human milk products derived from donor human milk, including fortifier, if ordered as medically necessary by a physician, physician assistant, or nurse practitioner licensed to practice in South Carolina and:

(1) in the case of pasteurized donor human milk:

(a) the insured newly born child is medically or physically unable to receive maternal breast milk or participate in breastfeeding; or

(b) the insured newly born child’s mother is medically or physically unable to produce maternal breast milk in sufficient quantities; or

(2) in the case of human milk product derived from donor human milk:

(a) the insured newly born child is younger than six months of age; or

(b) the physician, physician assistant, or nurse practitioner:

(i) determines that the insured newly born child’s body weight is below a health level established by the physician, physician assistant, or nurse practitioner; or

(ii) diagnoses the insured newly born child with a congenital or acquired condition that places the insured newly born child at a high risk for developing necrotizing enterocolitis or that may benefit from the use of the product.”

B. This SECTION takes effect January 1, 2022.

SECTION 3. Except where otherwise provided, this act takes effect upon approval by the Governor.

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