

Legislative Analysis



REGULATE PROCESSING AND DISTRIBUTION OF HUMAN BREAST MILK

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House Bill 4206 (reported from committee as H-6)
Sponsor: Rep. Erika Geiss

Analysis available at
<http://www.legislature.mi.gov>

House Bill 5547 (reported without amendment)
Sponsor: Rep. George T. Darany

Committee: Health Policy
Complete to 11-27-16

BRIEF SUMMARY: House Bill 4206 would create a new law to regulate the procurement, processing, storage, and distribution of human breast milk by individuals, hospitals, human milk banks, and human milk banking companies. It would classify certain offenses as felonies or civil infractions and prescribe penalties. House Bill 5547 amends the sentencing guidelines within the Code of Criminal Procedure to add the new felony offenses.

FISCAL IMPACT: MDARD currently has regulatory authority over state food safety and quality assurance programs. Program activities are authorized under the Food Law of 2000 (2000 PA 92). Appropriations for those activities in the 2016-17 fiscal year total \$14.0 million, with 93.0 authorized full-time equated positions. We have not yet obtained from the department an estimate of the cost of administering the human breast milk regulatory program proposed under House Bill 4206. To the extent that the bill does not provide for additional revenue to support the new program, new department program activities would be funded from existing resources.

The proposed amendment to require consultation with MDHHS would have modest fiscal implications for that department. This role may require up to ½ FTE position at an estimated cost of \$70,000 on an ongoing basis unless the department can utilize existing resources and personnel. MDHHS administers maternal and child health programs, including programs directed to new mothers and infants.

The bills add new felonies. The average cost of prison incarceration in a state facility is roughly \$34,900 per prisoner per year, a figure that includes various fixed administrative and operational costs. State costs for parole and felony probation supervision average about \$3,400 per supervised offender per year.

THE APPARENT PROBLEM:

Authorities such as the World Health Organization (WHO), Centers for Disease Control (CDC), and American Academy of Pediatrics (AAP) have recognized the positive impact of breastfeeding on lowering the risk of death from infectious diseases in the first two years of life and reducing the incidence of infant mortality. Because some women are unable to

produce milk, are unable to produce the amount needed, or are adoptive or foster parents, an industry has emerged in order to connect supply with need. However, at present that industry is largely unregulated. This legislation would seek to increase protections, and to protect an especially vulnerable population from unsafe, adulterated breast milk.

THE CONTENT OF THE BILL:

House Bill 4206 would create a new law to regulate the procurement, processing, storage, and distribution of human breast milk by individuals, hospitals, human milk banks (which are non-profit), and human milk banking companies (which are for-profit). It would not apply to mother-to-mother milk sharing groups or mothers feeding their own children. The bill would specify required disclosures and regulations for those organizations, and categorize certain acts as offenses.

Additionally, the new statute would place the responsibility for enforcing rules and penalizing violations with the Michigan Department of Agriculture and Rural Development (MDARD), in consultation with the Michigan Department of Health and Human Services (MDHHS).

House Bill 5547 amends the sentencing guidelines within the Code of Criminal Procedure to add the new felony offenses. The bills are tie-barred together, meaning neither would take effect unless both are enacted, and would take effect 90 days after enactment.

Offenses related to provision of human milk

House Bill 4206 designates six acts related to provision of human milk as offenses punishable by fines and/or imprisonment.

An individual, hospital, human milk bank, or a human milk banking company that knowingly provides adulterated human milk *to a child not the woman's own* is guilty as follows:

- If no physical injury or death, a state civil infraction and may be ordered to pay a civil fine of not more than \$5,000.
- If physical injury, a felony punishable by imprisonment for not more than five years, or a fine of not more than \$10,000 plus twice the amount of any economic benefit associated with the violation, or both.
- If death, a felony punishable by imprisonment for not more than 15 years, or a fine of not more than \$15,000 plus twice the amount of any economic benefit associated with the violation, or both.
 - "Economic benefit" in the latter two categories includes any collection or processing fee related to the violation.

These same three penalties apply when an individual, human milk bank, or human milk banking company provides raw human milk *for the purpose of human consumption*.

Screening of milk provided for another child

If a woman provides human milk for a child that is not her own, that woman must be screened for use of prescription drugs as determined by MDARD, in consultation with MDHHS, and the milk must be tested for common drugs of abuse, including nicotine, before the milk may be allowed under this act. This screening applies to milk provided to a hospital, milk bank, or milk banking company.

May not accept milk until mother is 180 days postpartum

Under the bill, an individual, human milk bank, or human milk banking company working with breastfeeding mothers in Michigan could only accept milk from a mother who was at least 180 days postpartum (unless provided an exception by the mother's medical professional). A knowing violation is a state civil infraction punishable by a civil fine of not more than \$5,000.

Required lactation support and education for participating mothers

The bill requires that a milk bank or milk banking company provide breastfeeding education and lactation support for its participating mothers, to ensure that the needs of the mothers' children are the priority, and that their children are adequately nourished by the mothers' own breast milk.

Milk distribution to hospitals, foster & adoptive parents of newborns

An individual, milk bank, or milk banking company operating or doing business in Michigan must, whenever possible, make every effort to ensure that human milk produced by and collected from mothers in Michigan is utilized to provide human milk for the vulnerable, premature, or ill infants in this state or for distribution to foster parents or adoptive parents in Michigan who wish to provide human milk for their foster or adoptive newborn infant children.

Disclosure of milk distribution to participating mothers

Milk banks and milk banking companies operating in Michigan must disclose to participating mothers what they do with all procured milk, regardless of whether it is accepted or rejected in a manner to be determined by MDARD in conjunction with MDHHS and milk banks and milk banking companies.

Oversight and enforcement assigned to Director of MDARD

The bill ascribes access to milk-related facilities and records for the purpose of detecting violations, as well as enforcement powers to the director of MDARD. Specifically, the director has free access at reasonable hours to any hospital, milk bank, milk banking company, or vehicle used to transport or hold the milk, for the purpose of evaluating the property or vehicle to determine if this act or rules promulgated under it are being violated. Upon payment or offer of payment, the director may also secure samples of any human milk in order to determine if the act or rules are being violated.

The director may examine the records of the hospital, milk bank, or milk banking company to obtain pertinent information about the milk, equipment, and personnel, and may copy records, while protecting confidentiality.

When necessary for the enforcement of this act, the director may seize without formal warrant any human milk for distribution in violation of this act or rules promulgated under this act. Also, milk which the director has reason to believe is **adulterated** (defined below) or misbranded must be marked as seized or embargoed, and may not be removed or disposed of without permission from the director or a court of competent jurisdiction.

Possible outcomes for seized milk

If milk is seized or embargoed, the director must file a petition in the applicable circuit court for a complaint for condemnation of the milk, with the milk stored appropriately during the investigation. The milk may be destroyed at the expense of the owner or, if proper processing or labelling would correct the issue, may be returned to the owner to correct, under the director's supervision and with the owner paying attendant costs. If the milk is not, in fact, adulterated, the director will remove the marking. If milk becomes adulterated during the course of the investigation, the state will pay the commercial value of the loss to the owner.

Definitions

- ***Adulterated:*** Breast milk that has been improperly processed, is contaminated with any poisonous or harmful substance that may render the milk injurious to an infant, or has any other condition that creates a risk to the public health, safety, or welfare.
- ***Human milk bank:*** organized service for "community benefit", a member in good standing of the Human Milk Banking Association of North America (HMBANA), a hospital based or affiliated organization, or other not-for-profit organization that is focused on procuring, processing, storing, and distributing human milk for use by those most in need, including, but not limited to, medically fragile, low birth weight, preterm babies, new mothers with delayed lactation, infants recovering from serious gut complications and surgery, or directly to a parent or entity with a prescription order, who is unable to nurse or is in need of additional human milk to support the child.
- ***Human milk banking company:*** a company, organization, or cooperative that engages in the practice of providing remuneration to lactating women for their expressed human milk or otherwise collects human milk. Remuneration does not include receipt of a breast pump or other supplies reasonably necessary for safe milk expression, storage, or transport.

House Bill 5547 would amend the Code of Criminal Procedure to classify four of the acts associated with the provision of raw human milk for human consumption as felonies (the remaining two would be civil infractions), and prescribe the sentencing guidelines. All four would be public safety offenses.

The following two would be classified as E felonies with a statutory maximum of five years imprisonment:

- Providing raw human milk for human consumption causing physical injury, and
- Financial gain by providing raw human milk for human consumption causing physical injury.

The following two would be classified as C felonies with a statutory maximum of 15 years imprisonment.

- Providing raw human milk for human consumption causing death, and
- Financial gain by providing raw human milk for human consumption causing death.

BACKGROUND:

As of November of 2016, California, Maryland, New York, and Texas have adopted various regulations defining and/or regulating human milk banks, and New Jersey was considering legislation.¹ New York, for example, requires that donors be periodically screened, and regulates collection and storage at milk banks. In Maryland, milk banks must acquire permits and meet certain inspection and testing standards. New Jersey's legislation would define and allow licensure of milk banks, and require that they follow HMBANA standards.²

ARGUMENTS:

For:

Premature and ill infants would not only benefit immediately from strengthened safety measures governing breast milk, say proponents, but those benefits would continue throughout their lives, as breast milk is linked to improved long term health outcomes. Infants with conditions such as necrotizing enterocolitis (or NEC)—a gastrointestinal complication that afflicts many premature infants and is a leader cause of death in this age group—especially benefit from easy access to safe breast milk. NEC affects 12% of premature babies, and claims the lives of one in four infants with NEC.

There is concern that, without regulations such as these, the breast milk industry could experience the same problems as were experienced in the blood industry in the 1970s and 80s, when diseases were transmitted by unregulated or under regulated blood transfusions.

Against:

Opponents of the bills say that the bill promotes nonprofit milk banks over for-profit milk banking companies, many of which have established standards they claim function better than those proposed in the bill. Further, they argue that the bill would codify standards used by the Human Milk Banking Association of North America (HMBANA), rather than federal or state rules.

For-profit organizations prioritize the health and safety of the milk and the child, but also seek to allow donor mothers to stay home with their own child as long as possible, by providing them with a money stream in exchange for their breast milk. The bills would negatively impact that goal by stating that a woman may not provide milk until 180 days postpartum, rather than the 90 days currently required by those companies. The possibility

¹ <http://www.azcentral.com/story/money/business/consumer/2015/07/07/state-regulations-breast-milk-banks/29844697/>

² <http://www.app.com/story/news/politics/new-jersey/2016/11/03/nj-senate-advances-milk-bank-standards/93265022/>

of selling excess breast milk after three months provides these mothers with income and the opportunity to delay return to work.

Response:

The concern, and reason for requiring women to wait for three or six months before providing milk, is that the high demand for milk, and the monetary benefits, will lead women to sell their milk rather than feeding it to their babies. A 90- or 180-day wait is intended to ensure that babies of poor women who may wish to sell their milk are guaranteed access for their first few months of life.

POSITIONS:

A representative of the Michigan Breastfeeding Network testified in support of the bills. (9-6-16)

A representative of Prolacta Bioscience testified in support of the bills. (9-6-16)

The following organizations support the bills:

Michigan Council for Maternal and Child Health (9-29-15)

Necrotizing Enterocolitis Society (9-29-15)

Black Mothers Breast Feeding Association (9-29-15)

Mothers' Milk Bank, Bronson Methodist Hospital—Kalamazoo (9-29-15)

American Academy of Pediatrics, Michigan Chapter (9-6-16)

Ascension Michigan (9-6-16)

American Association of University Women (9-6-16)

A representative of the Michigan Department of Agriculture and Rural Development testified and took no position on the bills. (9-6-16)

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.