

Legislative Analysis



REGULATE PROCESSING AND DISTRIBUTION OF HUMAN BREAST MILK

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House Bill 4206 (proposed substitute H-5, draft 2)
Sponsor: Rep. Erika Geiss

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

House Bill 5547 as introduced
Sponsor: Rep. George T. Darany

Committee: Health Policy
Complete to 9-3-16

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 (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).

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 raw 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, 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.

Compensated provision of milk

An individual, human milk bank, or human milk banking company that collects human milk and provides financial compensation or shares of stock for procuring, processing, distributing, or using human milk for the purpose of human construction is a **compensated donor** and shall not use the term "community benefit" to describe the company, its activities, or the collection of the milk.

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 ensure that, at a minimum, 50 percent of the human breast milk produced by participating mothers in a specific locality is distributed locally. Specifically and under the bill, the milk must be distributed (1) to hospitals for their neo-natal intensive care units; or (2) to local milk banks or milk banking companies, so they can provide milk for vulnerable premature or ill infants; or (3) to foster parents or adoptive parents who wish to provide breast milk for their newborn or infant children.

This requirement does not apply in the instance of an emergency milk shortage or if more milk is donated than need or demand requires. It also does not apply to a milk bank or milk banking company that also provides human milk-based human milk fortifier.

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 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 sale 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 designation which does not include a human milk banking company or its activities), a member in good standing of the Human Milk Banking Association of North America 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.

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 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.

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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.