

**SUBSTITUTE FOR
HOUSE BILL NO. 4206**

A bill to require individuals, hospitals, human milk banks, and human milk banking companies to comply with certain standards; to provide for education and support of certain breastfeeding mothers; to prescribe certain duties for state departments and agencies; and to prescribe penalties for the violation of this act.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 1. As used in this act:

2 (a) "Adulterated" means breast milk that is any of the
3 following:

4 (i) Has been improperly processed, including, but not limited
5 to, improper or unknown storage temperatures after receipt by a
6 human milk bank or human milk banking company or improper
7 pasteurization times or temperatures based on the pasteurized milk
8 ordinance as that term is defined in section 6 of the grade A milk

1 law of 2001, 2001 PA 266, MCL 288.476.

2 (ii) Is contaminated with any poisonous or deleterious
3 substance that may render the human milk injurious to the health of
4 a human infant, including, but not limited to, nicotine,
5 antibiotics, pathogens, chemicals, or foreign material as set forth
6 by the department, in consultation with the department of health
7 and human services, in the rules promulgated under this act.

8 (iii) Any other condition that creates a risk to the public
9 health, safety, or welfare.

10 (b) "Community benefit" means a program or activity that
11 provides treatment or promotes health and healing as a response to
12 identified community needs.

13 (c) "Department" means the department of agriculture and rural
14 development.

15 (d) "Director" means the director of the department.

16 (e) "Distribution" means removal of human milk from a human
17 milk bank or human milk banking company to any other location for
18 processing or storage or for the purpose of providing human milk to
19 a hospital or selling human milk to another entity.

20 (f) "Donor" means a lactating woman who voluntarily
21 contributes her own expressed breast milk to a human milk bank or
22 human milk banking company for use by an infant or child other than
23 her own. A donor may be provided supplies reasonably necessary for
24 safe milk expression, storage, or transport under this act.

25 (g) "Hospital" means that term as defined in section 5883 of
26 the public health code, 1978 PA 368, MCL 333.5883.

27 (h) "Human milk bank" means an organized service for community

1 benefit, a member in good standing of the Human Milk Banking
2 Association of North America, a hospital based or affiliated
3 organization, or other not-for-profit organization that is focused
4 on procuring, processing, storing, and distributing human milk for
5 use by those most in need, including, but not limited to, medically
6 fragile, low birth weight, preterm babies, new mothers with delayed
7 lactation, infants recovering from serious gut complications and
8 surgery, or directly to a parent or entity with a prescription
9 order, who is unable to nurse or is in need of additional human
10 milk to support the child.

11 (i) "Human milk banking company" means a company,
12 organization, or cooperative that engages in the practice of
13 providing remuneration to lactating women for their expressed human
14 milk or otherwise collects human milk. Remuneration does not
15 include receipt of a breast pump or other supplies reasonably
16 necessary for safe milk expression, storage, or transport.

17 (j) "Processing" means the use of rigorous protocols and
18 requirements based on scientific evidence and recommendation from
19 the Food and Drug Administration (FDA) and the Centers for Disease
20 Control and Prevention required to prepare, identify, and label
21 human milk in accordance with FDA requirements for use by the
22 patient.

23 (k) "Procuring" means obtaining human milk.

24 (l) "Storage" or "storing" means holding human milk in
25 connection with procuring or processing it before distribution.

26 Sec. 2. (1) Procuring, processing, storing, distributing, or
27 using human milk for the purpose of infant human consumption from a

1 human milk bank is a rendering of a service and not the sale of
2 human milk for profit or financial gain.

3 (2) An individual, a hospital, a human milk bank, or a human
4 milk banking company that procures, processes, stores, or
5 distributes human milk from a mother to nourish a child other than
6 her own shall not provide adulterated human milk for the purpose of
7 human consumption and shall comply with the standards set forth by
8 the department, in consultation with the department of health and
9 human services, and the rules promulgated by the department, in
10 consultation with the department of health and human services,
11 under this act. An individual, a hospital, a human milk bank, or a
12 human milk banking company that knowingly provides adulterated
13 human milk is guilty of 1 or more of the following:

14 (a) If the violation does not result in physical injury or
15 death, a state civil infraction and may be ordered to pay a civil
16 fine of not more than \$5,000.00.

17 (b) If the violation results in physical injury, a felony
18 punishable by imprisonment for not more than 5 years, or a fine of
19 not more than \$10,000.00 plus twice the amount of any economic
20 benefit associated with the violation, or both. For the purpose of
21 this subdivision and subdivision (c), "economic benefit" includes
22 any collection or processing fee related to the violation.

23 (c) If the violation results in death, a felony punishable by
24 imprisonment for not more than 15 years, or a fine of not more than
25 \$15,000.00 plus twice the amount of any economic benefit associated
26 with the violation, or both.

27 (3) Subsection (2) does not prohibit an individual, a

1 hospital, a human milk bank, or a human milk banking company from
2 being charged with, convicted of, or punished for any other
3 violation of law committed by that individual, hospital, human milk
4 bank, or human milk banking company while knowingly violating or
5 knowingly attempting to violate subsection (2), including the
6 underlying offense.

7 (4) If a woman provides human milk to a hospital, human milk
8 bank, or human milk banking company, that woman must be screened
9 for use of prescription drugs as determined by the department, in
10 consultation with the department of health and human services, and
11 the milk must be tested for common drugs of abuse, including, but
12 not limited to, nicotine before the milk may be allowed for use
13 under this act. Screening and testing are not required on human
14 milk collected from a mother exclusively for her own child.

15 Sec. 3. (1) An individual, a human milk bank, or a human milk
16 banking company that provides human milk for the purpose of human
17 consumption shall not provide raw human milk for the purpose of
18 human consumption and must comply with the rules promulgated under
19 this act. An individual, a human milk bank, or a human milk banking
20 company that knowingly violates this subsection is responsible for
21 or guilty of the following:

22 (a) If the violation does not result in physical injury or
23 death, a state civil infraction and may be ordered to pay a civil
24 fine of not more than \$5,000.00.

25 (b) If the violation results in physical injury, a felony
26 punishable by imprisonment for not more than 5 years, or a fine of
27 not more than \$10,000.00 plus twice the amount of any economic

1 benefit associated with the violation, or both. For the purpose of
2 this subdivision and subdivision (c), "economic benefit" includes
3 any collection or processing fee related to the violation.

4 (c) If the violation results in death, a felony punishable by
5 imprisonment for not more than 15 years, or a fine of not more than
6 \$15,000.00 plus twice the amount of any economic benefit associated
7 with the violation, or both.

8 (2) Subsection (1) does not prohibit an individual, a human
9 milk bank, or a human milk banking company from being charged with,
10 convicted of, or punished for any other violation of law committed
11 by that individual, human milk bank, or human milk banking company
12 while knowingly violating or knowingly attempting to violate
13 subsection (1), including the underlying offense.

14 Sec. 4. An individual, a human milk bank, or a human milk
15 banking company working with breastfeeding mothers in this state
16 shall only accept human milk from a mother who is at least 180 days
17 postpartum unless an exception is provided by authorization from a
18 licensed medical professional working directly with the mother
19 within the scope of his or her practice. An individual, a human
20 milk bank, or a human milk banking company that knowingly violates
21 this section is responsible for a state civil infraction and may be
22 ordered to pay a civil fine of not more than \$5,000.00.

23 Sec. 5. A human milk bank or human milk banking company shall
24 provide lactation support and education to mothers who are
25 providing human milk to ensure that the needs of nursing children
26 of participating mothers are the priority and that those nursing
27 children are adequately nourished by the mother's own milk.

1 Lactation support and education may include, but is not limited to,
2 working with hospital-based or community-based lactation support
3 groups.

4 Sec. 6. (1) An individual, human milk bank, or human milk
5 banking company operating or doing business in this state shall,
6 whenever possible, make every effort to ensure that human milk
7 produced by and collected from mothers in this state is utilized to
8 provide human milk for the vulnerable, premature, or ill infants in
9 this state, or for distribution to foster parents or adoptive
10 parents in this state who wish to provide human milk for their
11 foster or adoptive newborn infant children.

12 (2) A human milk bank or human milk banking company operating
13 in this state shall disclose to participating mothers what it does
14 with all of the procured human milk, regardless of whether the
15 human milk is accepted or rejected in a manner to be determined by
16 the department, in consultation with the department of health and
17 human services and in conjunction with human milk banks and human
18 milk banking companies.

19 Sec. 7. (1) The director has free access at reasonable hours
20 to any hospital, human milk bank, or human milk banking company,
21 including a vehicle used to transport or hold human milk, for the
22 purpose of evaluating that hospital, human milk bank, or human milk
23 banking company, or vehicle to determine if this act or rules
24 promulgated under this act are being violated. The director may
25 secure samples of any human milk, after paying or offering to pay
26 for the samples, to determine if this act or rules promulgated
27 under this act are being violated.

1 (2) The director may examine the records of the hospital,
2 human milk bank, or human milk banking company, to obtain pertinent
3 information about the human milk, supplies, and equipment
4 purchased, received, or used by, or persons employed by, the
5 hospital, human milk bank, or human milk banking company, or
6 location.

7 (3) The director may take photographs or copy records as part
8 of an evaluation. If a hospital, human milk bank, or human milk
9 banking company identifies by written document or mark that a
10 certain area or record contains visible trade secrets, the director
11 shall identify any photographs of that area or copies of that
12 record as being confidential and shall diligently protect the
13 confidentiality.

14 Sec. 8. (1) When necessary for the enforcement of this act,
15 the director may seize without formal warrant any human milk found
16 to be distributed, held for distribution, or exposed for sale in
17 violation of this act or rules promulgated under this act.

18 (2) If the director finds or has probable cause to believe
19 that any human milk is adulterated or so misbranded as to be
20 dangerous to public health or fraudulent, within the meaning of
21 this act, he or she shall affix to the human milk a tag or other
22 appropriate marking giving notice that the human milk is, or is
23 suspected of being, adulterated or misbranded and has been seized
24 or embargoed. A person shall not remove or dispose of the human
25 milk tagged or marked as embargoed or seized, by sale or otherwise,
26 until permission for removal or disposal is given by the director
27 or a court of competent jurisdiction.

1 (3) If human milk seized or embargoed under subsection (1) or
2 (2) is determined by the director to be adulterated or misbranded,
3 he or she shall cause a petition to be filed in the circuit court
4 in whose jurisdiction the human milk is seized or embargoed for a
5 complaint for condemnation of the human milk. Seized or embargoed
6 human milk shall be stored safely and at appropriate temperatures
7 during the period of investigation. Seized or embargoed human milk
8 may be destroyed at the expense of the claimant of the human milk,
9 under the supervision of the director, and the court may order the
10 payment of the costs, fees, storage, and other proper expenses by
11 the claimant of the human milk or his or her agents. If the court
12 finds that adulteration or misbranding can be corrected by proper
13 labeling or processing of the human milk, after entry of the order;
14 payment of the costs, fees, and expenses; and execution of a good
15 and sufficient bond conditioned that the human milk be labeled or
16 processed properly, the court may direct the human milk to be
17 delivered to the claimant for labeling or processing under the
18 director's supervision. The claimant shall pay the expense of the
19 supervision. The human milk shall be returned to the claimant of
20 the human milk on the representation to the court by the director
21 that the human milk is no longer in violation of this act and that
22 the expenses of supervision have been paid. If the director
23 determines that the human milk seized or embargoed is not
24 adulterated or misbranded, he or she shall remove the tag or other
25 marking. If, within the course of the investigation, previously
26 unadulterated human milk becomes adulterated, the state shall pay
27 the commercial value of the loss to the individual, hospital, human

1 milk bank, or human milk banking company from which the human milk
2 was seized or embargoed.

3 Sec. 9. This act does not apply to mother-to-mother human milk
4 sharing groups or mothers feeding their own children.

5 Enacting section 1. This act takes effect 90 days after the
6 date it is enacted into law.

7 Enacting section 2. This act does not take effect unless House
8 Bill No. 5547 of the 98th Legislature is enacted into law.