
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1001 Session of
2019

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MARCH 27, 2019

REFERRED TO COMMITTEE ON HEALTH, MARCH 27, 2019

AN ACT

1 Regulating milk banks that provide donor human milk in this
2 Commonwealth.

3 The General Assembly of the Commonwealth of Pennsylvania
4 hereby enacts as follows:

5 Section 1. Short title.

6 This act shall be known and may be cited as the Keystone
7 Mothers' Milk Bank Act.

8 Section 2. Legislative intent.

9 The General Assembly finds and declares as follows:

10 (1) A mother's own milk is the optimal nutrition for
11 newborn infants and is a public health goal for the delivery
12 of food to all infants.

13 (2) Medically vulnerable infants, including those born
14 prematurely, with low birth weights or with congenital or
15 acquired conditions, derive significant health benefits from
16 receiving human milk.

1 (3) Necrotizing enterocolitis is a devastating
2 complication that may result in partial or complete
3 destruction of the intestinal lining and may lead to both
4 short-term and life-long health consequences, including
5 premature death. An all-human-milk diet can significantly
6 lower the risk of necrotizing enterocolitis in medically
7 vulnerable infants, including those born prematurely.

8 (4) Mothers of medically vulnerable babies often face
9 unique obstacles to producing enough milk for their babies.
10 When a mother's own milk is not available, donor human milk
11 can provide a lifesaving health benefit for high-risk infants
12 as a supplement or bridge when determined to be medically
13 necessary.

14 (5) The American Academy of Pediatrics is a strong and
15 vocal proponent of the use of donor human milk for medically
16 fragile newborns when provided through properly regulated
17 milk banks.

18 (6) Children with a wide range of congenital or acquired
19 conditions may benefit from the use of donor human milk as a
20 component of treatment for their medical conditions when
21 their mother's own milk is unavailable or cannot meet all of
22 their needs.

23 (7) The use of donor milk is safe when appropriate
24 measures are used to screen donors and collect, store and
25 process the milk for distribution through milk banks licensed
26 by the Department of Health.

27 (8) Banked donor milk is predominantly pasteurized to
28 inactivate pathogens, tested for chemicals or substances that
29 could be injurious to high-risk infants and frozen for
30 storage and shipping. Human milk donors are carefully

1 medically screened and blood tested to ensure they are
2 healthy and that the milk is free from any infectious
3 diseases or substances that could be harmful to high-risk
4 infants.

5 (9) The Human Milk Banking Association of North America
6 is a professional association that establishes and maintains
7 current, rigorous guidelines for the operation of human milk
8 banks throughout North America.

9 Section 3. Definitions.

10 The following words and phrases when used in this act shall
11 have the meanings given to them in this section unless the
12 context clearly indicates otherwise:

13 "Act." This act and any rule or regulation adopted under
14 this act.

15 "American Academy of Pediatrics." An American professional
16 association of pediatricians that issues clinical guidelines
17 regarding the use of donor milk in the delivery of medically
18 necessary care to newborns and babies.

19 "Batch." A limited quantity or grouping of donor milk
20 sharing a common characteristic as further defined by the
21 department.

22 "Birth center." A freestanding health care facility for
23 childbirth where care is provided in the midwifery and wellness
24 model.

25 "Collection." The obtaining of donor milk from medically
26 screened donors by a milk bank licensed in this Commonwealth.

27 "Committee." The medical advisory committee established by a
28 milk bank in accordance with section 5(a).

29 "Department." The Department of Health of the Commonwealth.

30 "Dispensary." A center that has an agreement with a milk

1 bank for the distribution of milk from the milk bank by
2 prescription.

3 "Distribution." The delivery of medically ordered or
4 prescribed donor milk to a licensed acute care hospital, birth
5 center, lactation center, pharmacy, dispensary or medically
6 approved outpatient facility by a milk bank licensed in this
7 Commonwealth.

8 "Donor." A lactating woman with an excess supply of human
9 milk who:

10 (1) voluntarily contributes milk to a milk bank after
11 being medically screened and approved for milk donation; and

12 (2) receives no remuneration for the donation of milk.

13 "Donor milk." Human milk derived from a medically screened
14 donor that is voluntarily donated to a milk bank and processed
15 for distribution.

16 "HMBANA." The Human Milk Banking Association of North
17 America.

18 "Lactation center." A center whose sole or main purpose is
19 to provide support for and education about breastfeeding.

20 "License." A license issued by the department under this
21 act.

22 "Licensed acute care hospital." A hospital that is licensed
23 by the department under the act of July 19, 1979 (P.L.130,
24 No.48), known as the Health Care Facilities Act, and is equipped
25 and staffed for the treatment of medical or surgical conditions,
26 or both, in the acute or chronic stages, on an inpatient basis
27 of 24 or more hours.

28 "Licensee." A milk bank that holds a valid license under
29 this act.

30 "Medically screened." The process of or relating to the

1 process of evaluating prospective donors by a milk bank to
2 determine the acceptability of the donor milk based on the
3 donor's past medical history, medication use, current state of
4 health and indicated laboratory studies through a process as
5 approved by the department.

6 "Milk bank." An entity that collects donor milk from
7 medically screened human donors and distributes the donor milk
8 to medically fragile children other than the donor's own child
9 based on a health care provider's order or prescription, using
10 storage, processing and shipping methods required by the
11 department.

12 "Person." An individual, partnership, association,
13 corporation, institution, agency or other similar entity.

14 "Processing." The standards and techniques approved by the
15 department for inactivating pathogens in donor milk and ensuring
16 the safety of donor milk.

17 "Professional association." A professional association that
18 establishes and requires member compliance with satisfactory
19 guidelines for the operation of human milk banks as designated
20 by the department. The term includes HMBANA.

21 "Professional association guidelines." Guidelines issued by
22 a professional association that govern the operation of milk
23 banks belonging to the professional association.

24 "Satellite milk depot." An entity that has an ongoing
25 relationship with a licensed milk bank to collect and store
26 donor milk for shipping to the licensed milk bank.

27 "Secretary." The Secretary of Health of the Commonwealth.

28 "Storage." The method of holding and freezing donor milk
29 approved by the department in connection with the donor milk's
30 collection or processing prior to the distribution.

1 Section 4. Milk banks.

2 (a) Licensure.--An entity operating or seeking to operate as
3 a milk bank in this Commonwealth must apply to and be licensed
4 by the department.

5 (b) Application.--The department shall issue a license to an
6 applicant if:

7 (1) The applicant is in compliance with this act and has
8 submitted a completed application as developed by the
9 department that includes all the information required in
10 section 7.

11 (2) The entity meets one of the following requirements:

12 (i) Is certified as a member in good standing of
13 HMBANA.

14 (ii) Is certified as a member in good standing of a
15 nationally recognized professional organization for the
16 operation of milk banks.

17 (iii) Is determined to be in compliance with the
18 requirements of this act.

19 (c) Initial inspection.--Prior to the issuance of a license,
20 the department shall perform an inspection in accordance with
21 section 7(e).

22 (d) Denial.--

23 (1) An application that has not been approved within six
24 months of the date of the application shall be deemed denied.

25 (2) If the department denies an application, or the
26 application is deemed denied, the department shall provide
27 the applicant with a written explanation of the reason for
28 the denial.

29 (3) An applicant which is denied is entitled to a
30 hearing if the applicant requests a hearing within 30 days of

1 the receipt of the denial or within 30 days of the deemed
2 denial if no written explanation is received.

3 (e) Fee.--The department shall charge the following fees for
4 the administration and implementation of this act:

5 (1) An entity shall pay a \$1,000 fee for an initial
6 license.

7 (2) A licensee shall pay a \$250 fee for each license
8 renewal.

9 (f) Expiration.--A license issued under this act shall
10 expire two years after the date of the issuance of the license.

11 (g) Renewal.--A license issued under this act may be renewed
12 in accordance with the regulations promulgated by the department
13 and upon the payment of a renewal fee.

14 (h) Suspension and revocation.--

15 (1) The department may suspend or revoke a license
16 issued under this act if the department determines that, in
17 accordance with section 7, the licensee is not in compliance
18 with this act.

19 (2) Written notification and a hearing shall be provided
20 in accordance with section 7(h) prior to the suspension or
21 revocation.

22 (i) Operation prior to effective date.--A milk bank in
23 operation prior to the effective date of this section may
24 continue to operate pending a decision on its application if an
25 application is made within 120 days of the later of the
26 following:

27 (1) The effective date of this section.

28 (2) The date that an application for a license is first
29 made available to prospective licensees under this act.

30 Section 5. Operation of milk bank.

1 (a) Licensee requirements.--

2 (1) Each milk bank shall develop and ensure the
3 implementation of policies and procedures consistent with
4 professional association guidelines or the requirements of
5 this act.

6 (2) Each milk bank shall be operated by a managing
7 director responsible for the day-to-day operations of the
8 milk bank.

9 (3) A milk bank shall establish a medical advisory
10 committee to consult on milk bank operations, which shall be
11 composed of physicians and other allied health personnel with
12 experience in neonatology, blood or tissue banking, nutrition
13 and other related expertise. At least one member of the
14 committee must have experience in the field of infectious
15 diseases or biologics manufacturing.

16 (4) A milk bank shall have a medical director who is a
17 licensed physician with a minimum of four years' experience
18 in neonatology, pediatrics, blood banking, infectious disease
19 or a related field.

20 (5) A milk bank shall be overseen by a board of
21 directors or similar body, which shall be responsible for the
22 oversight of the milk bank's operating, regulatory and
23 compliance efforts and the work of the managing director, the
24 medical director and the committee.

25 (b) Record retention.--Each licensed milk bank shall
26 maintain the following records in a manner determined by the
27 department in an easily accessible location at the milk bank:

28 (1) An individual file on each milk donor, including the
29 donor's consent to participate in the program and the result
30 of each laboratory test performed prior to donation and

1 during the duration of the donation. Direct or indirect
2 identifying information for an individual donor may not be
3 disclosed except with the written consent of the individual
4 donor.

5 (2) Records providing for the tracing of each donated
6 milk container from donor to distribution shall include the
7 following:

8 (i) Each donor identified by an identification
9 number.

10 (ii) The information from each container's affixed
11 identification tag.

12 (iii) If used, the identity of the satellite milk
13 depot, the time and date of receipt by the satellite milk
14 depot and the information relating to the transportation
15 of the milk.

16 (3) The dates that the donor milk was pasteurized,
17 distributed and used.

18 (4) Identifying information for milk pooled from
19 multiple donors, which shall also be separately recorded and
20 maintained.

21 (5) Bacteriological testing and dates for each batch of
22 donor milk.

23 (6) Refrigeration and freezer temperatures.

24 (7) Tracking and shipping information for the
25 distribution of donor milk by facility or by specific
26 outpatient use.

27 (c) Disclosure of relationships.--A licensed milk bank
28 shall notify the department within 10 days of establishing a
29 relationship with a dispensary or satellite milk depot.

30 (d) License display.--A licensed milk bank shall display the

1 license in a prominent place at the milk bank's main location.
2 Section 6. Donation, processing and distribution of donor milk.

3 (a) Donor qualifications.--Potential donors of donor milk
4 shall:

5 (1) Be medically screened initially and periodically
6 reassessed to determine conditions and behaviors that may
7 affect the quality or nutritional value of the donor's milk
8 or do harm to the donor herself.

9 (2) Provide consent for the milk bank to contact the
10 donor's health care providers, who can grant approval for the
11 donor and the donor's baby to be medically screened and blood
12 tested to ensure the health of the potential donor and the
13 donor's baby and to ensure the donor milk is free of any
14 chemical, disease or substance that could injure an infant
15 receiving the milk.

16 (3) Be excluded from donation for a documented infection
17 by a bloodborne pathogen or for other acute or chronic
18 infectious diseases.

19 (4) Be temporarily precluded from donating milk if the
20 donor:

21 (i) Uses medications contraindicated during
22 breastfeeding or tobacco or other substances as may be
23 identified by the department.

24 (ii) Has a systemic chronic disease or nutritional
25 deficiency as identified by the donor's or the donor's
26 infant's health care provider.

27 (iii) Has a history of exposure to possible
28 environmental contaminants, including lead or mercury.

29 (iv) Lacks the ability to understand and follow
30 directions regarding the sanitary collection and storage

1 of donor milk.

2 (b) Donor milk processing.--Donor milk shall be processed in
3 accordance with the following:

4 (1) An approved pasteurization or processing method,
5 including the Holder pasteurization method or another method
6 approved by the department, the United States Food and Drug
7 Administration or a professional organization, shall be used
8 to inactivate pathogens in donor milk.

9 (2) Post-pasteurization bacteriologic cultures shall be
10 performed.

11 (3) Containers of unprocessed donor milk shall be
12 labeled with the donor's identification number and the date
13 of collection.

14 (4) Frozen, unprocessed donor milk held at a satellite
15 milk depot shall identify the location, along with the date
16 and time of receipt and transportation.

17 (5) Each container of processed donor milk shall be
18 properly labeled with the expiration date, batch number and
19 name of the milk bank specific to the milk contained in the
20 bottle.

21 (c) Storage.--Donor milk shall be stored in accordance with
22 the following:

23 (1) Proper refrigeration and freezer capability shall be
24 available at each milk bank, with appropriate thermometer
25 calibration performed no less frequently than annually. The
26 thermometer on each refrigerator and freezer used for the
27 storage of donor milk shall be visually or mechanically
28 monitored daily for possible fluctuations in temperature that
29 could impact the quality of the donor milk.

30 (2) Packing of processed milk shall be documented using

1 containers that are approved by the United States Food and
2 Drug Administration as food safe vessels for both heating and
3 freezing.

4 (3) Donor milk shall be stored and transported frozen at
5 a proper temperature and under conditions that protect the
6 milk from contamination, thawing and refreezing.

7 (4) Donor milk shall be shipped in clean, insulated
8 containers using packing material to minimize contamination
9 of the outside of the bottles during transportation.

10 Section 7. Duties of department.

11 (a) Licensure of milk banks.--The department shall:

12 (1) Regulate the operation of milk banks that handle and
13 distribute donor milk in this Commonwealth.

14 (2) Issue licenses to milk banks deemed compliant with
15 this act.

16 (b) Review of professional association guidelines.--

17 (1) The department shall review and approve professional
18 association guidelines to ensure that the guidelines in use
19 maintain the necessary requirements and standards of review
20 for the safe operation and certification of licensees in this
21 Commonwealth. If, at any time, the department determines that
22 the professional association guidelines do not maintain
23 necessary requirements and standards of review for the safe
24 operation and certification of licensees, licensees must
25 satisfy the requirements under paragraph (2).

26 (2) The department shall adopt standards and
27 requirements for licensure separate from those of the
28 professional association guidelines referenced in paragraph
29 (1) which the department determines are sufficient to
30 maintain the safe operation and certification of licensees.

1 (c) Milk bank compliance.--To be licensed by the department,
2 a milk bank must satisfy the professional association guidelines
3 referenced in subsection (b) (1) or the standards and
4 requirements established by the department under subsection (b)
5 (2), as applicable.

6 (d) Application requirements.--The department shall develop
7 a standard written application for a license, which shall
8 include at least the following:

9 (1) The name and location of the milk bank.

10 (2) The name and address of the managing director
11 responsible for the milk bank's day-to-day operations and of
12 the medical director of the milk bank.

13 (3) The education and experience of each person in a
14 supervisory or technical role in the operation of the milk
15 bank.

16 (4) A description of the physical facilities, locations,
17 equipment, sources of materials and methods of processing,
18 storage and distribution of donor milk.

19 (5) A description of each technical procedure used in
20 the routine operation of the milk bank.

21 (6) Any relationship between the applicant and either a
22 dispensary or satellite milk depot.

23 (7) Any other information required by the department.

24 (e) Inspection of facilities and documentation.--The
25 department shall inspect a milk bank's physical facilities and
26 the physical facilities of a dispensary or satellite milk depot
27 with which the licensee has a relationship and shall examine
28 all required documentation maintained by the milk bank prior to
29 licensure and at any time deemed necessary by the department.

30 (f) Contents of license.--A license shall display the

1 following information:

2 (1) The name and address of the licensee and the
3 location of all facilities, dispensaries and affiliated
4 satellite milk depots authorized under the license.

5 (2) The name and address of the managing director
6 responsible for the milk bank's day-to-day operations and of
7 the medical director of the milk bank.

8 (3) The signature of the secretary.

9 (g) Submission of professional association accreditation.--

10 (1) A licensee belonging to a professional association
11 shall submit the licensee's professional association
12 certification information to the department within 30 days of
13 each inspection and accreditation by the professional
14 association.

15 (2) A licensee belonging to a professional association
16 shall notify the department within 72 hours when membership
17 in a professional association is terminated for any reason.

18 (h) Revocations.--Before the department suspends or revokes
19 a license issued under this act, the department shall provide
20 written notification to the licensee specifying the reasons for
21 the revocation or suspension and indicating a time and place for
22 a hearing to be held within 30 days of the notification.

23 Section 8. Violations.

24 (a) Prohibitions.--The following shall be prohibited:

25 (1) The operation of a milk bank in this Commonwealth by
26 a person not licensed under this act.

27 (2) The direct or indirect sale of human milk for profit
28 or a service fee by a person not licensed under this act.

29 (3) Remuneration of value provided to a milk donor by an
30 entity, except as permitted under section 9(c).

1 (b) Penalties.--A violation of this section shall constitute
2 a misdemeanor of the third degree.

3 Section 9. Exceptions.

4 (a) Hospital.--A milk bank located in this Commonwealth and
5 regulated by the department through a hospital licensure process
6 shall be exempt from this act if the entity distributes donor
7 milk solely within that hospital to inpatients or outpatients.

8 (b) Availability of milk.--If facilitated by a milk bank
9 licensed under this act which lacks access to donor milk or a
10 specific type of milk ordered or prescribed to a Pennsylvania
11 resident, that donor milk may be procured from an out-of-State
12 milk bank approved by a professional organization or, if
13 necessary, by the department.

14 (c) Donor remuneration.--Notwithstanding the definitions of
15 "donor" and "donor milk" under section 3, the department may
16 exempt a milk bank from the requirement that donors provide milk
17 voluntarily for no remuneration. In determining whether to grant
18 this exception, the milk bank must demonstrate to the department
19 that:

20 (1) the exemption based on this limited circumstance was
21 sought prior to remunerating donors in this Commonwealth;

22 (2) the practices are satisfactorily maintained to
23 protect public health and the safety of the donor milk
24 recipient, the donor and the donor's baby, based on commonly
25 accepted medical standards; and

26 (3) any additional standards required by the department
27 reasonably necessary to ensure compliance with paragraph (2)
28 are implemented.

29 Section 10. Reports.

30 Starting in the second odd-numbered year after the effective

1 date of this section, and each odd-numbered year thereafter, the
2 department shall prepare a report on the operation of milk banks
3 in this Commonwealth in accordance with the following:

4 (1) The report shall include the following information:

5 (i) The number of licensed milk banks in this
6 Commonwealth.

7 (ii) The address, including the county, for each
8 licensed milk bank.

9 (iii) A summary of the amount of milk donated,
10 processed and distributed by each milk bank organized by
11 facility type.

12 (iv) Any other information deemed necessary by the
13 department.

14 (2) The report shall be provided to:

15 (i) The chairperson and minority chairperson of the
16 Health and Human Services Committee of the Senate.

17 (ii) The chairperson and minority chairperson of the
18 Health Committee of the House of Representatives.

19 Section 11. Licensure application and regulations.

20 (a) Application.--

21 (1) Upon the effective date of this subsection, the
22 department shall create an application for the licensure of
23 milk banks.

24 (2) The department shall begin accepting applications
25 for the licensure of milk banks 120 days after the effective
26 date of this subsection.

27 (b) Regulations.--The department may promulgate rules and
28 regulations to administer and enforce this act.

29 Section 12. Effective date.

30 This act shall take effect as follows:

1 (1) This section and section 11 of this act shall take
2 effect immediately.

3 (2) The remainder of this act shall take effect in 120
4 days.