
THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 811 Session of
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REFERRED TO HEALTH AND HUMAN SERVICES, AUGUST 7, 2019

AN ACT

1 Regulating milk banks that provide human donor 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.

17 (3) Necrotizing enterocolitis is a devastating

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

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

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

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

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

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

1 donor milk is free from any infectious diseases or substances
2 that could be harmful to high-risk infants.

3 Section 3. Definitions.

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

7 "Act." This act and any rule or regulation adopted under
8 this act.

9 "Batch." A limited quantity or grouping of donor milk
10 sharing a common characteristic as further defined by the
11 department.

12 "Birth center." A freestanding health care facility for
13 childbirth where care is provided in the midwifery and wellness
14 model.

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

17 "Committee." The medical advisory committee formed by a milk
18 bank in accordance with section 5(a)(6).

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

20 "Dispensary." A center that has an agreement with a milk
21 bank for the distribution of milk from the milk bank by
22 prescription.

23 "Distribution." The delivery of medically ordered or
24 prescribed donor milk to a licensed acute care hospital, birth
25 center, lactation center, pharmacy, dispensary, medically
26 approved outpatient facility or directly to an outpatient by a
27 milk bank licensed in this Commonwealth.

28 "Donor." Subject to the provisions of section 10, a
29 lactating woman with an excess supply of human milk who
30 voluntarily and without remuneration contributes milk to a milk

1 bank after being medically screened and approved for milk
2 donation.

3 "Donor milk." Subject to the provisions of section 10, human
4 milk derived from a properly screened donor that is voluntarily
5 donated without remuneration to a milk bank and processed for
6 distribution.

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

9 "License." A license issued by the department under this
10 act.

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

17 "Licensee." A milk bank that holds a valid license under
18 this act.

19 "Milk bank." An entity that collects donor milk from
20 properly screened human donors and distributes the donor milk to
21 medically fragile children, other than a donor's own child,
22 based on a health care provider's order or prescription, using
23 storage, processing and shipping methods required by the
24 department.

25 "NICU." The neonatal intensive care unit of a licensed acute
26 care hospital.

27 "Person." A natural person, partnership, association,
28 corporation, institution, agency or other similar entity.

29 "Processing." The standards and techniques approved by the
30 department for inactivating pathogens in donor milk and ensuring

1 the safety of donor milk.

2 "Professional association." A professional association that
3 establishes and requires member compliance with satisfactory
4 guidelines for the operation of human milk banks as designated
5 by the department.

6 "Professional association guidelines." Guidelines issued by
7 a professional association that govern the operation of milk
8 banks belonging to the professional association.

9 "Satellite milk depot." An entity that has an ongoing
10 relationship with a licensee to collect and store donor milk for
11 shipping to the licensee.

12 "Screening donors" or "donor screening process." The process
13 of evaluating prospective donors by a milk bank to determine the
14 acceptability of donor milk based on a donor's past medical
15 history, medication use, current state of health and indicated
16 laboratory studies through a process as approved by the
17 department.

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

19 "Storage." The method of holding and freezing donor milk as
20 approved by the department in connection with the donor milk's
21 collection or processing prior to distribution.

22 Section 4. Milk banks.

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

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

28 (1) The applicant is in compliance with this act and has
29 submitted a completed application as developed by the
30 department that includes all the information required in

1 section 7(d).

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

3 (i) is certified as a member in good standing of a
4 nationally recognized professional association for the
5 operation of milk banks; or

6 (ii) is otherwise determined to be in compliance
7 with the requirements of this act.

8 (c) Initial inspection.--

9 (1) Prior to the issuance of a license, the department
10 shall perform an inspection in accordance with section 7(e).

11 (2) Notwithstanding the requirement of paragraph (1),
12 the department need not inspect the facility if:

13 (i) the facility has a valid license or
14 accreditation from another state and the department is
15 satisfied that the other state's license addresses
16 appropriate health and safety concerns; or

17 (ii) the facility is registered and in good standing
18 with the United States Food and Drug Administration, and
19 the department has received confirmation that the
20 facility has satisfactorily addressed all observations
21 raised in previous inspections.

22 (d) Denial.--

23 (1) If the department denies an application, the
24 department shall provide the applicant with a written
25 explanation of the reason for the denial.

26 (2) An applicant that is denied a license is entitled to
27 a hearing if the applicant requests a hearing within 30 days
28 of the receipt of the denial.

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

1 (1) An applicant shall pay a \$1,000 fee for an initial
2 license.

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

5 (f) Expiration.--A license shall expire two years after the
6 date of the issuance of the license.

7 (g) Renewal.--A license may be renewed in accordance with
8 the regulations promulgated by the department and upon the
9 payment of a renewal fee.

10 (h) Suspension and revocation.--

11 (1) The department may suspend or revoke a license if
12 the department determines that, in accordance with section
13 7(h), the licensee is not in compliance with this act.

14 (2) The department shall provide written notification
15 and a hearing in accordance with section 7(h) prior to the
16 suspension or revocation of a license.

17 (i) Operation prior to effective date.--A milk bank in
18 operation prior to the effective date of this section may
19 continue to operate pending a decision on the milk bank's
20 application or pending a decision on whether the exemption
21 specified in section 10 applies, if the application is made
22 within 120 days of the later of the effective date of this
23 section or the date that applications for licenses are first
24 made available to prospective licensees under this act.

25 Section 5. Operation of milk bank.

26 (a) Licensee requirements.--

27 (1) Each milk bank shall develop and ensure the
28 implementation of policies and procedures consistent with the
29 requirements of this act.

30 (2) No donor milk or donor-milk-derived product may be

1 distributed by a milk bank without:

2 (i) testing to address associated risks as
3 identified by the guidelines of the milk bank under
4 section 7(c); and

5 (ii) otherwise satisfying the provisions of section
6 6.

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

10 (4) A board of directors or similar body shall oversee
11 the milk bank's operating, regulatory and compliance efforts
12 and the work of the managing director, the medical director
13 and the medical advisory committee.

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

18 (6) A milk bank shall have a medical advisory committee
19 to consult on milk bank operations, which advisory committee
20 shall be composed of physicians and other allied health
21 personnel with experience in neonatology, blood or tissue
22 banking, nutrition and other related expertise. At least one
23 member of the medical advisory committee must have experience
24 in the field of infectious diseases or biologics
25 manufacturing.

26 (b) Record retention.--A licensee shall maintain the
27 following records in a manner determined by the department in an
28 easily accessible location:

29 (1) An individual file on each milk donor, including the
30 donor's consent to participate in the program and the result

1 of each laboratory test performed prior to donation and
2 during the duration of the donation. Direct or indirect
3 identifying information for an individual donor may not be
4 disclosed except with the written consent of the individual
5 donor.

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

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

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

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

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

22 (6) Refrigeration and freezer temperatures.

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

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

29 (d) License display.--A licensee shall display the license
30 in a prominent place at the licensee's main location.

1 Section 6. Donation, processing and distribution of donor milk.

2 (a) Donor qualifications.--A potential donor shall:

3 (1) Undergo an initial medical screening and be
4 periodically reassessed to determine conditions and behaviors
5 that may affect the quality or nutritional value of the
6 donor's milk or that may do harm to the potential donor.

7 (2) Provide consent for the milk bank to contact:

8 (i) the donor's health care providers and medically
9 screen and blood test the potential donor to ensure the
10 health of the potential donor and to ensure the donor
11 milk is free of any chemical, disease or substance that
12 could injure an infant receiving the milk; and

13 (ii) the health care providers of the donor's
14 biological baby to verify that the baby is achieving
15 adequate growth, except in cases of bereavement,
16 surrogacy or adoption.

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

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

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

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

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

30 (iv) Lacks the ability to understand and follow

1 directions regarding the sanitary collection and storage
2 of donor milk.

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

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

10 (2) Postpasteurization bacteriologic cultures shall be
11 performed.

12 (3) Containers of unprocessed donor milk shall be
13 labeled with the donor's identification number and the date
14 of collection or the bar code that supplies this information.

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

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

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

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

1 (2) Packing of processed donor milk shall be done using
2 containers that are approved by the United States Food and
3 Drug Administration as food safe vessels for both heating and
4 freezing.

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

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

11 Section 7. Duties of department.

12 (a) General rule.--The department shall regulate the
13 operation of milk banks that handle and distribute donor milk in
14 this Commonwealth and issue licenses to milk banks in compliance
15 with the requirements of this act.

16 (b) Review of milk bank 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 guidelines in use by a professional association do not
23 maintain necessary requirements and standards of review for
24 the safe operation and certification of licensees, licensees
25 must satisfy the requirements of paragraph (2).

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

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

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

1 (2) Notwithstanding the requirement of paragraph (1),
2 the department need not inspect the facility if:

3 (i) the facility has a valid license or
4 accreditation from another state and the department is
5 satisfied that the other state's license addresses
6 appropriate health and safety concerns; or

7 (ii) the facility is registered and in good standing
8 with the United States Food and Drug Administration, and
9 the department has received confirmation that the
10 facility has satisfactorily addressed all observations
11 raised in previous inspections.

12 (f) Contents of license.--A license shall display the
13 following information:

14 (1) The name and address of the licensee and the
15 location of all facilities, dispensaries and affiliated
16 satellite milk depots authorized under the license.

17 (2) The name and address of the managing director
18 responsible for the day-to-day operations of the milk bank
19 and of the medical director of the milk bank.

20 (3) The signature of the secretary.

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

22 (1) A licensee belonging to a professional association
23 shall submit the licensee's professional association
24 certification information to the department within 30 days of
25 each inspection and accreditation by the professional
26 association.

27 (2) A licensee belonging to a professional association
28 must notify the department within 72 hours if membership in a
29 professional association is terminated for any reason.

30 (h) Revocations.--Before the department suspends or revokes

1 a license issued under this act, the department shall provide
2 written notification to the licensee specifying the reasons for
3 the revocation or suspension and indicating a time and place for
4 a hearing to be held within 30 days of the notification.

5 Section 8. Violations.

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

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

9 (2) The direct or indirect sale of human milk for profit
10 or a service fee by a milk bank not licensed under this act.

11 (3) Remuneration of value provided to a milk donor by a
12 milk bank, except as permitted under section 10.

13 (4) The sale or distribution of donor milk or any donor-
14 milk-derived product in violation of section 5(a)(2).

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

17 Section 9. Exceptions.

18 (a) Hospitals.--A milk bank located in this Commonwealth and
19 regulated by the department through a licensure process as a
20 hospital is exempt from this act if the hospital distributes
21 donor milk solely within the hospital to inpatients or
22 outpatients, or both.

23 (b) Availability of milk.--If facilitated by a milk bank
24 licensed under this act which lacks access to donor milk or a
25 specific type of milk ordered or prescribed to a Pennsylvania
26 resident, that donor milk may be procured from an out-of-State
27 milk bank accredited by a professional association or approved
28 by the department.

29 Section 10. Exemptions.

30 (a) General rule.--Notwithstanding the definitions of

1 "donor" and "donor milk" under section 3, the department may
2 exempt a milk bank from the requirement that donors provide
3 donor milk voluntarily and for no remuneration. In order to be
4 granted this exemption, the milk bank must satisfy the
5 following:

6 (1) The milk bank may not sell, donate or distribute
7 donor milk and donor-milk-derived products for which the
8 donor has been remunerated without testing for controlled
9 substances as determined by the department. The department
10 may, at any time, require additional testing for donor milk
11 and donor-milk-derived products.

12 (2) The milk bank may not sell, donate or distribute
13 donor milk and donor-milk-derived products for which the
14 donor has been remunerated without obtaining medical
15 verification that the donor's biological infant is achieving
16 adequate growth.

17 (3) The milk bank must meet or exceed any additional
18 standards required by the department reasonably necessary to
19 protect public health and the recipient of the donor milk,
20 the donor and the donor's baby.

21 (b) Construction.--If the milk bank is exempt under
22 subsection (a), the donor of the human milk shall be considered
23 a "donor" as defined in section 3 and the human milk provided by
24 the donor shall be considered "donor milk" as defined in section
25 3.

26 (c) Penalties.--A violation of this section shall constitute
27 a misdemeanor of the third degree.

28 (d) Applicability.--The provisions of subsection (a)(1) and
29 (2) shall not apply to milk banks that do not remunerate donors.
30 Section 11. Reports.

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

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

6 (i) The number of licensees in this Commonwealth.

7 (ii) The address, including the county, for each
8 licensee.

9 (iii) A summary of the amount of milk donated,
10 processed and distributed by each licensee 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 12. Licensure application.

20 Upon the effective date of this section, the department shall
21 create an application for the licensure of milk banks. The
22 department shall begin accepting applications for licensure of
23 milk banks 120 days after the effective date of this section.

24 Section 13. Regulations.

25 The department may promulgate rules and regulations to
26 administer and enforce this act.

27 Section 14. Effective date.

28 This act shall take effect as follows:

29 (1) This section and sections 12 and 13 shall take
30 effect immediately.

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