

KEYSTONE MOTHER'S MILK BANK ACT - ENACTMENT

Act of Feb. 12, 2020, P.L. 13, No. 7

Cl. 35

An Act

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

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

Section 1. Short title.

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

Section 2. Legislative intent.

The General Assembly finds and declares as follows:

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

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

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

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

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

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

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

(8) Banked donor milk is predominantly pasteurized to inactivate pathogens, tested for chemicals or substances that could be injurious to high-risk infants and frozen for storage and shipping. Human milk donors are carefully medically screened and blood tested to ensure they are healthy and that the donor milk is free from any infectious diseases or substances that could be harmful to high-risk infants.

Section 3. Definitions.

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

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

"Birth center." A birth center as defined in section 802.1 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

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

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

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

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

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

"Donor." Subject to the provisions of section 10, a lactating woman with an excess supply of human milk who:

- (1) voluntarily contributes milk to a milk bank after being medically screened and approved for milk donation; and
- (2) receives no remuneration for the donation of milk.

"Donor milk." Human milk derived from a donor that is donated to a milk bank and processed for distribution.

"Hospital." A hospital as defined in section 802.1 of the Health Care Facilities Act.

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

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

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

"Medically screened." The process of or relating to the process of evaluating prospective donors by a milk bank to determine the acceptability of the donor milk based on the donor's past medical history, medication use, current state of health and indicated laboratory studies through a process as approved by the department.

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

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

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

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

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

"Satellite milk depot." A collection site affiliated with a milk bank where a donor may drop off donor milk and that may be known as a transfer station.

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

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

Section 4. Milk banks.

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

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

(1) The applicant has submitted a completed application as developed by the department that includes all the information required in section 7(d).

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

(i) Is certified as a member in good standing of a professional association for the operation of milk banks; or

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

(c) Reliance on professional association.--

(1) The department shall accept the accreditation of a milk bank granted by a professional association, that is a nationally recognized accrediting body, to the extent the association's standards are determined to be acceptable by the department, when granting a license.

(2) The department shall maintain a list of approved professional associations that are nationally recognized accrediting bodies. The list shall be published on the department's publicly accessible Internet website.

(3) Upon request, a milk bank shall provide the department with copies of any finding or report issued by the accrediting body.

(d) Denial.--

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

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

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

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

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

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

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

(h) Suspension and revocation.--

(1) The department may suspend or revoke a license issued under this act if the department determines the licensee is not in compliance with this act.

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

(i) Operation prior to effective date.--A milk bank in operation prior to the effective date of this section may continue to operate pending a decision on the milk bank's application or pending decision on whether the exemption specified in section 10 applies if an application is made within 120 days of the later of the following:

(1) The effective date of this section.

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

Section 5. Operation of milk bank.

(a) Licensee requirements.--

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

(2) No donor milk or donor-milk-derived product may be distributed by a milk bank without:

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

(ii) otherwise satisfying the provisions of section 6.

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

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

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

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

(7) A milk bank shall provide to the department on an annual basis a summary of the amount of milk donated, processed and distributed by the milk bank within this Commonwealth.

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

(1) An individual file on each milk donor, including the donor's consent to participate in the program and the result of each laboratory test performed prior to donation and during the duration of the donation. Direct or indirect identifying information for an individual donor may not be disclosed except with the written consent of the individual donor. The information in this subsection is exempt from access under the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law.

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

(i) Each donor identified by an identification number.

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

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

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

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

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

(6) Refrigeration and freezer temperatures.

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

(8) Upon the request of the department, the milk bank shall provide information to be included in the department's report on the operation of milk banks required under section 11.

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) Lacks the ability to understand and follow directions regarding the sanitary collection and storage of donor milk.

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

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

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

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

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

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

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

(1) Proper refrigeration and freezer capability shall be available at each milk bank, with appropriate thermometer calibration performed no less frequently than annually. The thermometer on each refrigerator and freezer used for the storage of donor milk shall be visually or mechanically monitored daily for possible fluctuations in temperature that could impact the quality of the donor milk. The temperatures shall be recorded and maintained by each milk bank for a period of one year.

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

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

(4) Donor milk shall be shipped in clean, insulated containers using packing material to minimize contamination of the outside of the bottles during transportation, or as otherwise required by the department.

Section 7. Duties of department.

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

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

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

(b) Review of professional association guidelines.--

(1) The department shall review and approve professional association guidelines to ensure that the guidelines in use maintain the necessary requirements and standards of review for the safe operation and accreditation of licensees in this Commonwealth, and shall transmit to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin a list of professional associations that have approved guidelines. If, at any time, the department determines that the professional association guidelines do not maintain necessary requirements and standards of review for the safe operation and accreditation of licensees, licensees must satisfy the requirements under paragraph (2).

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

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

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

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

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

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

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

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

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

(7) Any other information required by the department.

(e) Inspection of facilities and documentation.--The following shall apply:

(1) Whenever the department receives a complaint or has other reasonable grounds to believe that a violation of this act has occurred, the department may, without notice to the licensee, survey any service, facility or portion of the licensee related to the suspected violation.

(2) For either issuance of a new license or renewals, the department need not inspect the milk bank if the milk bank meets at least two of the following:

(i) the milk bank has a valid license or accreditation from another state and the department is satisfied that the other state's license addresses appropriate health and safety concerns;

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

(iii) The milk bank has been accredited by a professional association that is a nationally recognized accrediting body to the extent the association's standards are determined to be acceptable by the department.

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

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

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

(3) The signature of the secretary.

(g) Submission of professional association accreditation.--

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

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

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

Section 8. Violations.

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

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

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

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

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

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

Section 9. Exceptions.

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

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

Section 10. Exemptions.

(a) General rule.--Notwithstanding the definitions of "donor" and "donor milk" under section 3, the department may exempt a milk bank from the requirement that donors provide donor milk voluntarily and for no remuneration. In order to be granted this exemption, the milk bank must satisfy the following:

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

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

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

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

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

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

Section 11. Reports.

Starting in the second odd-numbered year after the effective date of this section, and each odd-numbered year thereafter,

the department shall prepare a report on the operation of milk banks in this Commonwealth in accordance with the following:

- (1) The report shall include the following information:
 - (i) The number of licensed milk banks in this Commonwealth.
 - (ii) The address, including the county, for each licensed milk bank.
 - (iii) A summary of the amount of milk donated, processed and distributed by each milk bank organized by facility type.
 - (iv) Any other information deemed necessary by the department.
- (2) The report shall be provided to:
 - (i) The chairperson and minority chairperson of the Health and Human Services Committee of the Senate.
 - (ii) The chairperson and minority chairperson of the Health Committee of the House of Representatives.

Section 12. Licensure application.

Upon the effective date of this section, the department shall create an application for the licensure of milk banks. The department shall begin accepting applications for licensure of milk banks 180 days after the effective date of this section.

Section 13. Regulations.

The department shall promulgate rules and regulations to administer and enforce this act.

Section 14. Effective date.

This act shall take effect as follows:

- (1) The following provisions shall take effect immediately:
 - (i) This section.
 - (ii) Section 12.
 - (iii) Section 13.
- (2) The remainder of this act shall take effect in 180 days.