AN ACT

Regulating milk banks that provide human donor 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.

(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. Milk donors are carefully screened and
blood tested to ensure the donors 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:

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

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

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

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

"Committee." The medical advisory committee formed 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 voluntarily and without remuneration contributes milk to a milk bank.
bank after being medically screened and approved for milk
donation.

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

"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.

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

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

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

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

"Person." A natural person, 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." An entity that has an ongoing relationship with a licensee to collect and store donor milk for shipping to the licensee.

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

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

"Storage." The method of holding and freezing donor milk as approved by the department in connection with the donor milk's collection or processing prior to 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 is in compliance with this act and 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
       nationally recognized professional association for the
       operation of milk banks; or
   (ii) is otherwise determined to be in compliance
       with the requirements of this act.
(c) Initial inspection.--
   (1) Prior to the issuance of a license, the department
       shall perform an inspection in accordance with section 7(e).
   (2) Notwithstanding the requirement of paragraph (1),
       the department need not inspect the facility if:
       (i) the facility 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; or
       (ii) the facility 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.
(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 applicant 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 shall expire two years after the date of the issuance of the license.

(g) Renewal.--A license 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 if the department determines that, in accordance with section 7(h), 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 a decision on whether the exemption specified in section 10 applies, if the application is made within 120 days of the later of the effective date of this section or the date that applications for licenses are 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 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 have a medical advisory committee to consult on milk bank operations, which advisory committee 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 medical advisory committee must have experience in the field of infectious diseases or biologics manufacturing.

(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

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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.

(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 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 that is separately recorded and maintained.

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

(6) Refrigeration and freezer temperatures.

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

(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 licensee's main location.
Section 6. Donation, processing and distribution of donor milk.

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

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

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

   (i) the 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; and

   (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 and 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 methods 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) Postpasteurization 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 this information.

(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.
(2) Packing of processed donor milk shall be done 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 donor 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.

Section 7. Duties of department.

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

(b) Review of milk bank 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 certification of licensees in this Commonwealth. If, at any time, the department determines that the guidelines in use by a professional association do not maintain necessary requirements and standards of review for the safe operation and certification of licensees, licensees must satisfy the requirements of paragraph (2).

(2) The department shall adopt standards and requirements for licensure separate from those of the professional association guidelines under paragraph (1) which the department determines are sufficient to maintain the safe operation and certification of licensees.
(c) Milk bank compliance.--To be licensed by the department, a milk bank must satisfy either the guidelines of the professional association under 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.--

1. The department shall inspect a milk bank's physical facilities and the physical facilities of any dispensary or milk depot with which the licensee has a relationship and shall examine all required documentation maintained by the milk bank prior to licensure and when deemed necessary by the department.
(2) Notwithstanding the requirement of paragraph (1), the department need not inspect the facility if:

(i) the facility 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; or

(ii) the facility 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.

(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 day-to-day operations of the milk bank 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 must notify the department within 72 hours if 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) Hospitals.--A milk bank located in this Commonwealth and
regulated by the department through a licensure process as a
hospital is exempt from this act if the hospital distributes
donor milk solely within the hospital to inpatients or
outpatients, or both.

(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.
Beginning 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 licensees in this Commonwealth.
   (ii) The address, including the county, for each licensee.
   (iii) A summary of the amount of milk donated, processed and distributed by each licensee 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 120 days after the effective date of this section.

Section 13. Regulations.

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

Section 14. Effective date.

This act shall take effect as follows:

(1) This section and sections 12 and 13 shall take effect immediately.
(2) The remainder of this act shall take effect in 120 days.