

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL**No. 1001** Session of
2019

INTRODUCED BY OBERLANDER, YOUNGBLOOD, TOEPEL, KINSEY,
SCHLOSSBERG, KAUFFMAN, SCHLEGEL CULVER, SIMMONS, OTTEN, SIMS,
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ECKER, BROWN, FEE, MALAGARI, DUSH AND O'MARA, MARCH 27, 2019

AS AMENDED ON THIRD CONSIDERATION, IN SENATE, FEBRUARY 3, 2020

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 DONOR 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. A BIRTH CENTER AS DEFINED IN SECTION 802.1 OF THE ACT OF <--~~
25 JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE HEALTH CARE
26 FACILITIES ACT.

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

29 "Committee." The medical advisory committee established by a
30 milk bank in accordance with section ~~5(a)~~ 5(A) (6). <--

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

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

5 "Distribution." The delivery of medically ordered or
6 prescribed donor milk to a licensed acute care hospital, birth
7 center, lactation center, pharmacy, dispensary ~~or~~, medically <--
8 approved outpatient facility OR DIRECTLY TO AN OUTPATIENT by a <--
9 milk bank licensed in this Commonwealth.

10 "Donor." ~~A~~ SUBJECT TO THE PROVISIONS OF SECTION 10, A <--
11 lactating woman with an excess supply of human milk who:

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

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

15 ~~"Donor milk." Human SUBJECT TO THE PROVISIONS OF SECTION 10, <--~~
16 ~~HUMAN milk derived from a medically screened donor that is~~
17 ~~voluntarily donated WITHOUT REMUNERATION to a milk bank and <--~~
18 ~~processed for distribution.~~

19 ~~"HMBANA." The Human Milk Banking Association of North <--~~
20 ~~America. HUMAN MILK DERIVED FROM A DONOR THAT IS DONATED TO A <--~~
21 ~~MILK BANK AND PROCESSED FOR DISTRIBUTION.~~

22 "HOSPITAL." A HOSPITAL AS DEFINED IN SECTION 802.1 OF THE <--
23 HEALTH CARE FACILITIES ACT.

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

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

28 ~~"Licensed acute care hospital." A hospital that is licensed <--~~
29 ~~by the department under the act of July 19, 1979 (P.L.130,~~
30 ~~No.48), known as the Health Care Facilities Act, and is equipped~~

1 ~~and staffed for the treatment of medical or surgical conditions,~~
2 ~~or both, in the acute or chronic stages, on an inpatient basis~~
3 ~~of 24 or more hours.~~

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

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

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

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

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

23 "Professional association." A professional association that
24 establishes and requires member compliance with satisfactory
25 guidelines for the operation of human milk banks as designated
26 by the department. ~~The term includes HMBANA.~~ <--

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

30 "Satellite milk depot." ~~An entity that has an ongoing~~ <--

1 ~~relationship with a licensed milk bank to collect and store~~
2 ~~donor milk for shipping to the licensed milk bank.~~ A COLLECTION <--
3 SITE AFFILIATED WITH A MILK BANK WHERE A DONOR MAY DROP OFF
4 DONOR MILK AND THAT MAY BE KNOWN AS A TRANSFER STATION.

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

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

9 Section 4. Milk banks.

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

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

15 (1) The applicant ~~is in compliance with this act and has~~ <--
16 submitted a completed application as developed by the
17 department that includes all the information required in
18 section 7 7(D). <--

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

20 ~~(i) Is certified as a member in good standing of~~ <--
21 ~~HMBANA.~~

22 ~~(ii) (I) Is certified as a member in good standing~~ <--
23 ~~of a nationally recognized professional organization~~ <--
24 ASSOCIATION for the operation of milk banks-; OR <--

25 ~~(iii) (II) Is OTHERWISE determined to be in~~ <--
26 compliance with the requirements of this act.

27 ~~(c) Initial inspection. Prior to the issuance of a license,~~ <--

28 ~~(C) INITIAL INSPECTION.~~ <--

29 ~~(1) PRIOR TO THE ISSUANCE OF A LICENSE, the department~~
30 ~~shall perform an inspection in accordance with section 7(e).~~

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 (C) RELIANCE ON PROFESSIONAL ASSOCIATION.-- <--

13 (1) THE DEPARTMENT SHALL ACCEPT THE ACCREDITATION OF A
14 MILK BANK GRANTED BY A PROFESSIONAL ASSOCIATION, THAT IS A
15 NATIONALLY RECOGNIZED ACCREDITING BODY, TO THE EXTENT THE
16 ASSOCIATION'S STANDARDS ARE DETERMINED TO BE ACCEPTABLE BY
17 THE DEPARTMENT, WHEN GRANTING A LICENSE.

18 (2) THE DEPARTMENT SHALL MAINTAIN A LIST OF APPROVED
19 PROFESSIONAL ASSOCIATIONS THAT ARE NATIONALLY RECOGNIZED
20 ACCREDITING BODIES. THE LIST SHALL BE PUBLISHED ON THE
21 DEPARTMENT'S PUBLICLY ACCESSIBLE INTERNET WEBSITE.

22 (3) UPON REQUEST, A MILK BANK SHALL PROVIDE THE
23 DEPARTMENT WITH COPIES OF ANY FINDING OR REPORT ISSUED BY THE
24 ACCREDITING BODY.

25 (d) Denial.--

26 ~~(1) An application that has not been approved within six~~ <--
27 ~~months of the date of the application shall be deemed denied.~~

28 ~~(2)~~ (1) If the department denies an application, ~~or the~~ <--
29 ~~application is deemed denied,~~ the department shall provide
30 the applicant with a written explanation of the reason for

1 the denial.

2 ~~(3)~~ (2) An applicant ~~which is denied~~ THAT IS DENIED A <--
3 LICENSE is entitled to a hearing if the applicant requests a
4 hearing within 30 days of the receipt of the denial ~~or within~~ <--
5 ~~30 days of the deemed denial if no written explanation is~~
6 ~~received.~~

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

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

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

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

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

18 (h) Suspension and revocation.--

19 (1) The department may suspend or revoke a license
20 issued under this act if the department determines ~~that, in~~ <--
21 ~~accordance with section 7-7(H),~~ the licensee is not in <--
22 compliance with this act.

23 (2) ~~Written~~ THE DEPARTMENT SHALL PROVIDE WRITTEN <--
24 notification and a hearing ~~shall be provided~~ in accordance <--
25 with section 7(h) prior to the suspension or revocation OF A <--
26 LICENSE.

27 (i) Operation prior to effective date.--A milk bank in
28 operation prior to the effective date of this section may
29 continue to operate pending a decision on ~~its application~~ THE <--
30 MILK BANK'S APPLICATION OR PENDING DECISION ON WHETHER THE

1 EXEMPTION SPECIFIED IN SECTION 10 APPLIES if an application is
2 made within 120 days of the later of the following:

3 (1) The effective date of this section.

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

6 Section 5. Operation of milk bank.

7 (a) Licensee requirements.--

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

12 (2) NO DONOR MILK OR DONOR-MILK-DERIVED PRODUCT MAY BE <--
13 DISTRIBUTED BY A MILK BANK WITHOUT:

14 (I) TESTING TO ADDRESS ASSOCIATED RISKS AS
15 IDENTIFIED BY THE GUIDELINES OF THE MILK BANK UNDER
16 SECTION 7(C); AND

17 (II) OTHERWISE SATISFYING THE PROVISIONS OF SECTION
18 6.

19 ~~(2)~~ (3) Each milk bank shall be operated by a managing <--
20 director responsible for the day-to-day operations of the
21 milk bank.

22 (4) A BOARD OF DIRECTORS OR SIMILAR BODY SHALL OVERSEE <--
23 THE MILK BANK'S OPERATING, REGULATORY AND COMPLIANCE EFFORTS
24 AND THE WORK OF THE MANAGING DIRECTOR, THE MEDICAL DIRECTOR
25 AND THE MEDICAL ADVISORY COMMITTEE.

26 (5) A MILK BANK SHALL HAVE A MEDICAL DIRECTOR WHO IS A
27 LICENSED PHYSICIAN WITH A MINIMUM OF FOUR YEARS' EXPERIENCE
28 IN NEONATOLOGY, PEDIATRICS, BLOOD BANKING, INFECTIOUS DISEASE
29 OR A RELATED FIELD.

30 ~~(3)~~ (6) A milk bank shall establish a medical advisory <--

1 committee to consult on milk bank operations, which shall be
2 composed of physicians and other allied health personnel with
3 experience in neonatology, blood or tissue banking, nutrition
4 and other related expertise. At least one member of the
5 committee must have experience in the field of infectious
6 diseases or biologics manufacturing.

7 ~~(4) A milk bank shall have a medical director who is a~~ <--
8 ~~licensed physician with a minimum of four years' experience~~
9 ~~in neonatology, pediatrics, blood banking, infectious disease~~
10 ~~or a related field.~~

11 ~~(5) A milk bank shall be overseen by a board of~~
12 ~~directors or similar body, which shall be responsible for the~~
13 ~~oversight of the milk bank's operating, regulatory and~~
14 ~~compliance efforts and the work of the managing director, the~~
15 ~~medical director and the committee.~~

16 (7) A MILK BANK SHALL PROVIDE TO THE DEPARTMENT ON AN <--
17 ANNUAL BASIS A SUMMARY OF THE AMOUNT OF MILK DONATED,
18 PROCESSED AND DISTRIBUTED BY THE MILK BANK WITHIN THIS
19 COMMONWEALTH.

20 (b) Record retention.--~~Each licensed milk bank~~ A LICENSEE <--
21 shall maintain the following records in a manner determined by
22 the department in an easily accessible location ~~at the milk~~ <--
23 ~~bank:~~

24 (1) An individual file on each milk donor, including the
25 donor's consent to participate in the program and the result
26 of each laboratory test performed prior to donation and
27 during the duration of the donation. Direct or indirect
28 identifying information for an individual donor may not be
29 disclosed except with the written consent of the individual
30 donor. THE INFORMATION IN THIS SUBSECTION IS EXEMPT FROM <--

1 ACCESS UNDER THE ACT OF FEBRUARY 14, 2008 (P.L.6, NO.3),
2 KNOWN AS THE RIGHT-TO-KNOW LAW.

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

6 (i) Each donor identified by an identification
7 number.

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

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

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

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

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

21 (6) Refrigeration and freezer temperatures.

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

25 (8) UPON THE REQUEST OF THE DEPARTMENT, THE MILK BANK <--
26 SHALL PROVIDE INFORMATION TO BE INCLUDED IN THE DEPARTMENT'S
27 REPORT ON THE OPERATION OF MILK BANKS REQUIRED UNDER SECTION
28 11.

29 (c) Disclosure of relationships.--A ~~licensed milk bank~~ <--
30 LICENSEE shall notify the department within 10 days of <--

1 establishing a relationship with a dispensary or satellite milk
2 depot.

3 (d) License display.--A ~~licensed milk bank~~ LICENSEE shall <--
4 display the license in a prominent place at the milk bank's main
5 location.

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

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

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

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

20 (2) PROVIDE CONSENT FOR THE MILK BANK TO CONTACT: <--

21 (I) THE POTENTIAL DONOR'S HEALTH CARE PROVIDERS AND
22 MEDICALLY SCREEN AND BLOOD TEST THE POTENTIAL DONOR TO
23 ENSURE THE HEALTH OF THE POTENTIAL DONOR AND TO ENSURE
24 THE DONOR MILK IS FREE OF ANY CHEMICAL, DISEASE OR
25 SUBSTANCE THAT COULD INJURE AN INFANT RECEIVING THE MILK.

26 (II) THE HEALTH CARE PROVIDERS OF THE DONOR'S
27 BIOLOGICAL BABY TO VERIFY THAT THE BABY IS ACHIEVING
28 ADEQUATE GROWTH, EXCEPT IN CASES OF BEREAVEMENT,
29 SURROGACY OR ADOPTION.

30 (3) Be excluded from donation for a documented infection

1 by a bloodborne pathogen or for other acute or chronic
2 infectious diseases.

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

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

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

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

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

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

18 (1) An approved pasteurization or processing method,
19 including the Holder AND VAT pasteurization method or another <--
20 method approved by the department, the United States Food and
21 Drug Administration or a professional ~~organization~~ <--
22 ASSOCIATION, shall be used to inactivate pathogens in donor <--
23 milk.

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

26 (3) Containers of unprocessed donor milk shall be
27 labeled with the donor's identification number and the date
28 of collection; OR THE BAR CODE THAT SUPPLIES THE INFORMATION <--
29 REQUIRED UNDER THIS PARAGRAPH.

30 (4) Frozen, unprocessed donor milk held at a satellite

1 milk depot shall identify the location, along with the date
2 and time of receipt and transportation.

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

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

9 (1) Proper refrigeration and freezer capability shall be
10 available at each milk bank, with appropriate thermometer
11 calibration performed no less frequently than annually. The
12 thermometer on each refrigerator and freezer used for the
13 storage of donor milk shall be visually or mechanically
14 monitored daily for possible fluctuations in temperature that
15 could impact the quality of the donor milk. THE TEMPERATURES <--
16 SHALL BE RECORDED AND MAINTAINED BY EACH MILK BANK FOR A
17 PERIOD OF ONE YEAR.

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

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

25 (4) Donor milk shall be shipped in clean, insulated
26 containers using packing material to minimize contamination
27 of the outside of the bottles during transportation, OR AS <--
28 OTHERWISE REQUIRED BY THE DEPARTMENT.

29 Section 7. Duties of department.

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

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

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

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

6 (1) The department shall review and approve professional
7 association guidelines to ensure that the guidelines in use
8 maintain the necessary requirements and standards of review
9 for the safe operation and ~~certification~~ ACCREDITATION of <--
10 licensees in this Commonwealth, AND SHALL TRANSMIT TO THE <--
11 LEGISLATIVE REFERENCE BUREAU FOR PUBLICATION IN THE
12 PENNSYLVANIA BULLETIN A LIST OF PROFESSIONAL ASSOCIATIONS
13 THAT HAVE APPROVED GUIDELINES. If, at any time, the
14 department determines that the professional association
15 guidelines do not maintain necessary requirements and
16 standards of review for the safe operation and ~~certification~~ <--
17 ACCREDITATION of licensees, licensees must satisfy the <--
18 requirements under paragraph (2).

19 (2) The department shall adopt standards and
20 requirements for licensure separate from those of the
21 professional association guidelines referenced in paragraph
22 (1) which the department determines are sufficient to
23 maintain the safe operation and ~~certification~~ ACCREDITATION <--
24 of licensees.

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

30 (d) Application requirements.--The department shall develop

1 a standard written application for a license, which shall
2 include at least the following:

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

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

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

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

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

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

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

18 ~~(e) Inspection of facilities and documentation. The~~ <--

19 (E) INSPECTION OF FACILITIES AND DOCUMENTATION.--THE <--

20 FOLLOWING SHALL APPLY:

21 ~~(1) THE department shall inspect a milk bank's physical~~ <--
22 ~~facilities and the physical facilities of a dispensary or~~
23 ~~satellite milk depot with which the licensee has a~~
24 ~~relationship and shall examine all required documentation~~
25 ~~maintained by the milk bank prior to licensure and at any~~
26 ~~time deemed necessary by the department.~~

27 ~~(2) NOTWITHSTANDING THE REQUIREMENT OF PARAGRAPH (1),~~ <--
28 ~~THE DEPARTMENT NEED NOT INSPECT THE FACILITY IF:~~

29 (1) WHENEVER THE DEPARTMENT RECEIVES A COMPLAINT OR HAS <--
30 OTHER REASONABLE GROUNDS TO BELIEVE THAT A VIOLATION OF THIS

1 ACT HAS OCCURRED, THE DEPARTMENT MAY, WITHOUT NOTICE TO THE
2 LICENSEE, SURVEY ANY SERVICE, FACILITY OR PORTION OF THE
3 LICENSEE RELATED TO THE SUSPECTED VIOLATION.

4 (2) FOR EITHER ISSUANCE OF A NEW LICENSE OR RENEWALS,
5 THE DEPARTMENT NEED NOT INSPECT THE MILK BANK IF THE MILK
6 BANK MEETS AT LEAST TWO OF THE FOLLOWING:

7 (I) THE ~~FACILITY~~ MILK BANK HAS A VALID LICENSE OR <--
8 ACCREDITATION FROM ANOTHER STATE AND THE DEPARTMENT IS
9 SATISFIED THAT THE OTHER STATE'S LICENSE ADDRESSES
10 APPROPRIATE HEALTH AND SAFETY CONCERNS;

11 (II) THE ~~FACILITY~~ MILK BANK IS REGISTERED AND IN <--
12 GOOD STANDING WITH THE UNITED STATES FOOD AND DRUG
13 ADMINISTRATION, AND THE DEPARTMENT HAS RECEIVED
14 CONFIRMATION THAT THE FACILITY HAS SATISFACTORILY
15 ADDRESSED ALL OBSERVATIONS RAISED IN PREVIOUS
16 INSPECTIONS.

17 (III) THE MILK BANK HAS BEEN ACCREDITED BY A <--
18 PROFESSIONAL ASSOCIATION THAT IS A NATIONALLY RECOGNIZED
19 ACCREDITING BODY TO THE EXTENT THE ASSOCIATION'S
20 STANDARDS ARE DETERMINED TO BE ACCEPTABLE BY THE
21 DEPARTMENT.

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

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

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

30 (3) The signature of the secretary.

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

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

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

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

15 Section 8. Violations.

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

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

19 (2) The direct or indirect sale of human milk for profit
20 or a service fee by a ~~person~~ MILK BANK not licensed under <--
21 this act.

22 (3) Remuneration of value provided to a milk donor by an <--
23 ~~entity~~ A MILK BANK, except as permitted under section 9(e) <--
24 10. <--

25 (4) THE SALE OR DISTRIBUTION OF DONOR MILK OR ANY DONOR- <--
26 MILK-DERIVED PRODUCT IN VIOLATION OF SECTION 5(A) (2).

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

29 Section 9. Exceptions.

30 (a) Hospital.--A milk bank located in this Commonwealth and

1 regulated by the department through a hospital licensure process
2 shall be exempt from this act if the entity distributes donor
3 milk solely within that hospital to inpatients or outpatients.

4 (b) Availability of milk.--If facilitated by a milk bank
5 licensed under this act which lacks access to donor milk or a
6 specific type of milk ordered or prescribed to a Pennsylvania
7 resident, that donor milk may be procured from an out-of-State
8 milk bank ~~approved~~ ACCREDITED by a professional ~~organization~~ <--
9 ASSOCIATION or, ~~if necessary,~~ APPROVED by the department. <--

10 SECTION 10. EXEMPTIONS. <--

11 ~~(c) Donor remuneration~~ (A) GENERAL RULE.--Notwithstanding <--
12 the definitions of "donor" and "donor milk" under section 3, the
13 department may exempt a milk bank from the requirement that
14 donors provide DONOR milk voluntarily AND for no remuneration. <--
15 In ~~determining whether to grant this exception, the milk bank~~ <--
16 ~~must demonstrate to the department that:~~

17 ~~(1) the exemption based on this limited circumstance was~~
18 ~~sought prior to remunerating donors in this Commonwealth;~~

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

23 ~~(3) any additional standards required by the department~~
24 ~~reasonably necessary to ensure compliance with paragraph (2)~~
25 ~~are implemented.~~ ORDER TO BE GRANTED THIS EXEMPTION, THE MILK <--
26 BANK MUST SATISFY THE FOLLOWING:

27 (1) THE MILK BANK MAY NOT SELL, DONATE OR DISTRIBUTE
28 DONOR MILK AND DONOR-MILK-DERIVED PRODUCTS FOR WHICH THE
29 DONOR HAS BEEN REMUNERATED WITHOUT TESTING FOR CONTROLLED
30 SUBSTANCES AS DETERMINED BY THE DEPARTMENT. THE DEPARTMENT

1 MAY, AT ANY TIME, REQUIRE ADDITIONAL TESTING FOR DONOR MILK
2 AND DONOR-MILK-DERIVED PRODUCTS.

3 (2) THE MILK BANK MAY NOT SELL, DONATE OR DISTRIBUTE
4 DONOR MILK AND DONOR-MILK-DERIVED PRODUCTS FOR WHICH THE
5 DONOR HAS BEEN REMUNERATED WITHOUT OBTAINING MEDICAL
6 VERIFICATION THAT THE DONOR'S BIOLOGICAL INFANT IS ACHIEVING
7 ADEQUATE GROWTH.

8 (3) THE MILK BANK MUST MEET OR EXCEED ANY ADDITIONAL
9 STANDARDS REQUIRED BY THE DEPARTMENT REASONABLY NECESSARY TO
10 PROTECT PUBLIC HEALTH AND THE RECIPIENT OF THE DONOR MILK,
11 THE DONOR AND THE DONOR'S BABY.

12 (B) CONSTRUCTION.--IF THE MILK BANK IS EXEMPT UNDER
13 SUBSECTION (A), THE DONOR OF THE HUMAN MILK SHALL BE CONSIDERED
14 A "DONOR" AS DEFINED IN SECTION 3 AND THE HUMAN MILK PROVIDED BY
15 THE DONOR SHALL BE CONSIDERED "DONOR MILK" AS DEFINED IN SECTION
16 3.

17 (C) PENALTIES.--A VIOLATION OF THIS SECTION SHALL CONSTITUTE
18 A MISDEMEANOR OF THE THIRD DEGREE.

19 (D) APPLICABILITY.--THE PROVISIONS OF SUBSECTION (A) (1) AND
20 (2) SHALL NOT APPLY TO MILK BANKS THAT DO NOT REMUNERATE DONORS.
21 Section ~~10~~ 11. Reports. <--

22 Starting in the second odd-numbered year after the effective
23 date of this section, and each odd-numbered year thereafter, the
24 department shall prepare a report on the operation of milk banks
25 in this Commonwealth in accordance with the following:

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

27 (i) The number of licensed milk banks in this
28 Commonwealth.

29 (ii) The address, including the county, for each
30 licensed milk bank.

1 (iii) A summary of the amount of milk donated,
2 processed and distributed by each milk bank organized by
3 facility type.

4 (iv) Any other information deemed necessary by the
5 department.

6 (2) The report shall be provided to:

7 (i) The chairperson and minority chairperson of the
8 Health and Human Services Committee of the Senate.

9 (ii) The chairperson and minority chairperson of the
10 Health Committee of the House of Representatives.

11 ~~Section 11. Licensure application and regulations.~~ <--

12 ~~(a) Application.~~

13 ~~(1) Upon the effective date of this subsection, the~~
14 ~~department shall create an application for the licensure of~~
15 ~~milk banks.~~

16 ~~(2) The department shall begin accepting applications~~
17 ~~for the licensure of milk banks 120 days after the effective~~
18 ~~date of this subsection.~~

19 ~~(b) Regulations. The department may promulgate rules and~~
20 ~~regulations to administer and enforce this act.~~

21 SECTION 12. LICENSURE APPLICATION. <--

22 UPON THE EFFECTIVE DATE OF THIS SECTION, THE DEPARTMENT SHALL
23 CREATE AN APPLICATION FOR THE LICENSURE OF MILK BANKS. THE
24 DEPARTMENT SHALL BEGIN ACCEPTING APPLICATIONS FOR LICENSURE OF
25 MILK BANKS ~~120~~ 180 DAYS AFTER THE EFFECTIVE DATE OF THIS <--
26 SECTION.

27 SECTION 13. REGULATIONS.

28 THE DEPARTMENT ~~MAY~~ SHALL PROMULGATE RULES AND REGULATIONS TO <--
29 ADMINISTER AND ENFORCE THIS ACT.

30 Section ~~12~~ 14. Effective date. <--

1 This act shall take effect as follows:

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

4 (1) THE FOLLOWING PROVISIONS SHALL TAKE EFFECT <--
5 IMMEDIATELY:

6 (I) THIS SECTION.

7 (II) SECTION 12.

8 (III) SECTION 13.

9 (2) The remainder of this act shall take effect in ~~120~~ <--
10 180 days. <--