
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 AND DUSH, MARCH 27, 2019

SENATOR BROOKS, HEALTH AND HUMAN SERVICES, IN SENATE, AS
AMENDED, NOVEMBER 18, 2019

AN ACT

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

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

5 Section 1. Short title.

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

8 Section 2. Legislative intent.

9 The General Assembly finds and declares as follows:

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

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

1 receiving human milk.

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

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

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

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

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

28 (8) Banked donor milk is predominantly pasteurized to
29 inactivate pathogens, tested for chemicals or substances that
30 could be injurious to high-risk infants and frozen for

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

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

10 Section 3. Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

18 ~~"HMBANA." The Human Milk Banking Association of North~~ <--
19 ~~America.~~

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

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

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

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

1 this act.

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

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

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

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

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

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

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

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

30 "Storage." The method of holding and freezing donor milk

1 approved by the department in connection with the donor milk's
2 collection or processing prior to the distribution.

3 Section 4. Milk banks.

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

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

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

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

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

16 ~~(ii) (I) Is certified as a member in good standing~~ <--
17 ~~of a nationally recognized professional organization for~~
18 ~~the operation of milk banks;~~ OR <--

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

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

22 (C) INITIAL INSPECTION.-- <--

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

25 (2) NOTWITHSTANDING THE REQUIREMENT OF PARAGRAPH (1), <--
26 THE DEPARTMENT NEED NOT INSPECT THE FACILITY IF:

27 (I) THE FACILITY HAS A VALID LICENSE OR
28 ACCREDITATION FROM ANOTHER STATE AND THE DEPARTMENT IS
29 SATISFIED THAT THE OTHER STATE'S LICENSE ADDRESSES
30 APPROPRIATE HEALTH AND SAFETY CONCERNS; OR

1 (II) THE FACILITY IS REGISTERED AND IN GOOD STANDING
2 WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION, AND
3 THE DEPARTMENT HAS RECEIVED CONFIRMATION THAT THE
4 FACILITY HAS SATISFACTORILY ADDRESSED ALL OBSERVATIONS
5 RAISED IN PREVIOUS INSPECTIONS.

6 (d) Denial.--

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

9 ~~(2)~~ (1) If the department denies an application, or the <--
10 application is deemed denied, the department shall provide
11 the applicant with a written explanation of the reason for
12 the denial.

13 ~~(3)~~ (2) An applicant ~~which is denied~~ THAT IS DENIED A <--
14 LICENSE is entitled to a hearing if the applicant requests a
15 hearing within 30 days of the receipt of the denial ~~or within <--~~
16 ~~30 days of the deemed denial if no written explanation is-~~
17 ~~received.~~

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

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

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

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

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

29 (h) Suspension and revocation.--

30 (1) The department may suspend or revoke a license

1 issued under this act if the department determines that, in
2 accordance with section 7 7(H), the licensee is not in <--
3 compliance with this act.

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

8 (i) Operation prior to effective date.--A milk bank in
9 operation prior to the effective date of this section may
10 continue to operate pending a decision on ~~its application~~ THE <--
11 MILK BANK'S APPLICATION OR PENDING DECISION ON WHETHER THE
12 EXEMPTION SPECIFIED IN SECTION 10 APPLIES if an application is
13 made within 120 days of the later of the following:

14 (1) The effective date of this section.

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

17 Section 5. Operation of milk bank.

18 (a) Licensee requirements.--

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

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

25 (I) TESTING TO ADDRESS ASSOCIATED RISKS AS
26 IDENTIFIED BY THE GUIDELINES OF THE MILK BANK UNDER
27 SECTION 7(C); AND

28 (II) OTHERWISE SATISFYING THE PROVISIONS OF SECTION
29 6.

30 ~~(2)~~ (3) Each milk bank shall be operated by a managing <--

1 director responsible for the day-to-day operations of the
2 milk bank.

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

7 (5) 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 ~~(3)~~ (6) A milk bank shall establish a medical advisory <--
12 committee to consult on milk bank operations, which shall be
13 composed of physicians and other allied health personnel with
14 experience in neonatology, blood or tissue banking, nutrition
15 and other related expertise. At least one member of the
16 committee must have experience in the field of infectious
17 diseases or biologics manufacturing.

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

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

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

1 (1) An individual file on each milk donor, including the
2 donor's consent to participate in the program and the result
3 of each laboratory test performed prior to donation and
4 during the duration of the donation. Direct or indirect
5 identifying information for an individual donor may not be
6 disclosed except with the written consent of the individual
7 donor.

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

11 (i) Each donor identified by an identification
12 number.

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

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

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

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

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

26 (6) Refrigeration and freezer temperatures.

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

30 (c) Disclosure of relationships.--A ~~licensed milk bank~~

<--

1 LICENSEE shall notify the department within 10 days of <--
2 establishing a relationship with a dispensary or satellite milk
3 depot.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 Section 7. Duties of department.

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

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

30 (2) Issue licenses to milk banks deemed compliant with

1 this act.

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

3 (1) The department shall review and approve professional
4 association guidelines to ensure that the guidelines in use
5 maintain the necessary requirements and standards of review
6 for the safe operation and certification of licensees in this
7 Commonwealth. If, at any time, the department determines that
8 the professional association guidelines do not maintain
9 necessary requirements and standards of review for the safe
10 operation and certification of licensees, licensees must
11 satisfy the requirements under paragraph (2).

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

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

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

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

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

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

1 bank.

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

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

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

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

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

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

12 FOLLOWING SHALL APPLY:

13 (1) THE department shall inspect a milk bank's physical
14 facilities and the physical facilities of a dispensary or
15 satellite milk depot with which the licensee has a
16 relationship and shall examine all required documentation
17 maintained by the milk bank prior to licensure and at any
18 time deemed necessary by the department.

19 (2) NOTWITHSTANDING THE REQUIREMENT OF PARAGRAPH (1), <--
20 THE DEPARTMENT NEED NOT INSPECT THE FACILITY IF:

21 (I) THE FACILITY HAS A VALID LICENSE OR
22 ACCREDITATION FROM ANOTHER STATE AND THE DEPARTMENT IS
23 SATISFIED THAT THE OTHER STATE'S LICENSE ADDRESSES
24 APPROPRIATE HEALTH AND SAFETY CONCERNS;

25 (II) THE FACILITY IS REGISTERED AND IN GOOD STANDING
26 WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION, AND
27 THE DEPARTMENT HAS RECEIVED CONFIRMATION THAT THE
28 FACILITY HAS SATISFACTORILY ADDRESSED ALL OBSERVATIONS
29 RAISED IN PREVIOUS INSPECTIONS.

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

1 following information:

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

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

8 (3) The signature of the secretary.

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

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

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

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

23 Section 8. Violations.

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

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

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

30 (3) Remuneration of value provided to a milk donor by an <--

1 ~~entity~~ A MILK BANK, except as permitted under section 9(e) <--

2 10. <--

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

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

7 Section 9. Exceptions.

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

12 (b) Availability of milk.--If facilitated by a milk bank
13 licensed under this act which lacks access to donor milk or a
14 specific type of milk ordered or prescribed to a Pennsylvania
15 resident, that donor milk may be procured from an out-of-State
16 milk bank ~~approved~~ ACCREDITED by a professional organization or, <--
17 ~~if necessary,~~ APPROVED by the department. <--

18 SECTION 10. EXEMPTIONS. <--

19 ~~(c) Donor remuneration~~ (A) GENERAL RULE.--Notwithstanding <--
20 the definitions of "donor" and "donor milk" under section 3, the
21 department may exempt a milk bank from the requirement that
22 donors provide DONOR milk voluntarily AND for no remuneration. <--

23 ~~In determining whether to grant this exception, the milk bank~~ <--
24 ~~must demonstrate to the department that:~~

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

27 ~~(2) the practices are satisfactorily maintained to~~
28 ~~protect public health and the safety of the donor milk~~
29 ~~recipient, the donor and the donor's baby, based on commonly~~
30 ~~accepted medical standards; and~~

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

5 (1) THE MILK BANK MAY NOT SELL, DONATE OR DISTRIBUTE
6 DONOR MILK AND DONOR-MILK-DERIVED PRODUCTS FOR WHICH THE
7 DONOR HAS BEEN REMUNERATED WITHOUT TESTING FOR CONTROLLED
8 SUBSTANCES AS DETERMINED BY THE DEPARTMENT. THE DEPARTMENT
9 MAY, AT ANY TIME, REQUIRE ADDITIONAL TESTING FOR DONOR MILK
10 AND DONOR-MILK-DERIVED PRODUCTS.

11 (2) THE MILK BANK MAY NOT SELL, DONATE OR DISTRIBUTE
12 DONOR MILK AND DONOR-MILK-DERIVED PRODUCTS FOR WHICH THE
13 DONOR HAS BEEN REMUNERATED WITHOUT OBTAINING MEDICAL
14 VERIFICATION THAT THE DONOR'S BIOLOGICAL INFANT IS ACHIEVING
15 ADEQUATE GROWTH.

16 (3) THE MILK BANK MUST MEET OR EXCEED ANY ADDITIONAL
17 STANDARDS REQUIRED BY THE DEPARTMENT REASONABLY NECESSARY TO
18 PROTECT PUBLIC HEALTH AND THE RECIPIENT OF THE DONOR MILK,
19 THE DONOR AND THE DONOR'S BABY.

20 (B) CONSTRUCTION.--IF THE MILK BANK IS EXEMPT UNDER
21 SUBSECTION (A), THE DONOR OF THE HUMAN MILK SHALL BE CONSIDERED
22 A "DONOR" AS DEFINED IN SECTION 3 AND THE HUMAN MILK PROVIDED BY
23 THE DONOR SHALL BE CONSIDERED "DONOR MILK" AS DEFINED IN SECTION
24 3.

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

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

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

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

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

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

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

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

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

14 (2) The report shall be provided to:

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

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

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

20 ~~(a) Application.~~

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

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

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

29 SECTION 12. LICENSURE APPLICATION. <--

30 UPON THE EFFECTIVE DATE OF THIS SECTION, THE DEPARTMENT SHALL

1 CREATE AN APPLICATION FOR THE LICENSURE OF MILK BANKS. THE
2 DEPARTMENT SHALL BEGIN ACCEPTING APPLICATIONS FOR LICENSURE OF
3 MILK BANKS 120 DAYS AFTER THE EFFECTIVE DATE OF THIS SECTION.
4 SECTION 13. REGULATIONS.

5 THE DEPARTMENT MAY PROMULGATE RULES AND REGULATIONS TO
6 ADMINISTER AND ENFORCE THIS ACT.

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

8 This act shall take effect as follows:

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

11 (1) THE FOLLOWING PROVISIONS SHALL TAKE EFFECT <--
12 IMMEDIATELY:

13 (I) THIS SECTION.

14 (II) SECTION 12.

15 (III) SECTION 13.

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