

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL**No. 2516** Session of
2018

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BOBACK, HAHN, GILLEN, BARBIN, WARD, CEPHAS, BRADFORD AND
CRUZ, JUNE 19, 2018

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES,
AS AMENDED, SEPTEMBER 25, 2018

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 weight or with congenital or
15 acquired conditions, derive significant health benefits from

1 receiving human milk.

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

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

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

26 (8) Banked donor milk is predominantly pasteurized to
27 remove pathogens and frozen for storage and shipping.
28 Volunteer donors are carefully screened and blood tested to
29 ensure that the volunteers are healthy and that the milk is
30 free from any chemicals, diseases or substances that could be

1 damaging to high-risk infants.

2 (9) The Human Milk Banking Association of North America
3 is a professional association that established and maintains
4 current, rigorous guidelines for the operation of human milk
5 banks throughout North America.

6 Section 3. Definitions.

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

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

11 "HMBANA." The Human Milk Banking Association of North
12 America.

13 "Hospital." A hospital licensed by the department under the
14 act of July 19, 1979 (P.L.130, No.48), known as the Health Care
15 Facilities Act.

16 "Milk bank." An entity which collects and stores donated
17 human milk for distribution in accordance with an order or
18 prescription from a health care provider.

19 "Satellite milk depot." An entity that regularly collects
20 and stores donor milk for a licensed milk bank for the purposes
21 of holding and shipping.

22 Section 4. Milk banks.

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

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

28 (1) The applicant has submitted a completed application
29 developed by the department and including all the information
30 required in section 7.

1 (2) The entity is:

2 (i) certified as a member in good standing of the
3 HMBANA;

4 (ii) certified as a member in good standing of a
5 nationally recognized accrediting organization for the
6 operation of milk banks; or

7 (iii) determined to be in compliance with the
8 requirements of this act.

9 (c) Initial inspection.--Prior to the issuance of a license,
10 the department shall perform an inspection in accordance with
11 section 7.

12 (d) Denial.--

13 (1) An application that has not been approved within six
14 months of the date of the application shall be deemed denied.

15 (2) If the department denies an application, or the
16 application is deemed denied, the department shall provide
17 the applicant with a written explanation of the reason for
18 the denial.

19 (3) An applicant which is denied is entitled to a
20 hearing if the applicant requests a hearing within 30 days of
21 the receipt of the denial or within 30 days of the deemed
22 denial if no written explanation is received.

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

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

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

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

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

4 (h) Suspension and revocation.--

5 (1) The department may suspend or revoke a license
6 issued under this act if the department determines, in
7 accordance with section 7, the licensee is not in compliance
8 with this act.

9 (2) Written notification and a hearing shall be provided
10 in accordance with section 7 prior to the suspension or
11 revocation.

12 (i) Operation prior to effective date.--If an application is
13 submitted within 180 days of the effective date of this section,
14 an entity operating as a milk bank prior to the effective date
15 of this section may continue to operate without a license until
16 the department approves or denies the application.

17 Section 5. Operation of milk bank.

18 (a) Duties of director.--Each milk bank shall be operated by
19 a director who shall do all of the following:

20 (1) Develop and implement policies and procedures
21 consistent with the HMBANA guidelines and the requirements of
22 this act.

23 (2) Appoint a medical director who is a licensed
24 physician with a minimum of four years' experience in
25 neonatology, pediatrics, blood banking or a related field.

26 (3) Appoint a medical advisory committee for the milk
27 bank which shall include physicians and other allied health
28 personnel who have experience in neonatology, blood banking,
29 nutrition and other related expertise. At least one member
30 must have experience in the field of infectious diseases. The

1 committee shall be consulted on the appointment of the
2 medical director and shall oversee the operation of the milk
3 bank and develop governing policies.

4 (b) Record retention.--Each licensed milk bank shall
5 maintain the following records in a manner determined by the
6 department in an easily accessible location at the milk bank:

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

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

17 (i) Each donor identified by an identification
18 number.

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

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

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

26 (4) Identifying information for milk pooled from
27 multiple donors shall also be separately recorded and
28 maintained.

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

1 (6) Refrigerating and freezer temperatures.

2 (7) Tracking and shipping organization for the operation
3 of milk banks, within 30 days of each inspection and
4 accreditation of the milk bank.

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

7 Section 6. Process of donation and distribution.

8 (a) Donor qualifications.--Potential donors who volunteer to
9 provide donor milk, shall:

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

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

20 (3) Be permanently excluded from donation for a history
21 of or current behavior that puts her at an increased risk for
22 bloodborne pathogens or other acute or chronic infectious
23 diseases.

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

26 (i) Uses medications, tobacco, alcohol or other
27 substances.

28 (ii) Has a systemic chronic disease or nutritional
29 deficiency.

30 (iii) Has been exposed to possible environmental

1 contaminants.

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

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

7 (1) An approved pasteurization or processing method,
8 including the Holder pasteurization method or another method
9 approved by the HMBANA, shall be used to remove pathogens
10 from donor milk.

11 (2) Post pasteurization bacteriologic cultures shall be
12 performed.

13 (3) Containers of unprocessed donor milk shall be
14 labeled with the donor's identification number and the date
15 of collection.

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

19 ~~(5) Packaging of processed milk must be documented using <--~~
20 ~~Bisphenol A and phthalate free containers that are approved~~
21 ~~by the United States Food and Drug Administration as food-~~
22 ~~safe vessels for both heating and freezing.~~ Each container of
23 processed donor milk shall be properly labeled with the
24 expiration date, batch number and name of the milk bank
25 specific to the milk contained in the bottle. Labeling on
26 each container shall be made compatible with hospital donor
27 milk inventory and feeding systems.

28 ~~(6) Donor milk shall be stored and transported at a <--~~
29 ~~proper temperature to protect the milk from contamination,~~
30 ~~thawing and refreezing.~~

1 ~~(7) Donor milk shall be shipped in clean, insulated~~
2 ~~containers using packing material to minimize contamination~~
3 ~~of the outside of the bottles during transportation. Clean~~
4 ~~techniques shall be used to pack the milk in order to ensure~~
5 ~~the milk remains frozen.~~

6 ~~(c) Storage. Proper refrigeration and freezer capability~~

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 AT A
21 PROPER TEMPERATURE TO PROTECT THE MILK FROM CONTAMINATION,
22 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. CLEAN
26 TECHNIQUES SHALL BE USED TO PACK THE MILK IN ORDER TO ENSURE
27 THE MILK REMAINS FROZEN.

28 Section 7. Duties of department.

29 (a) Oversight of milk banks.--The department shall regulate
30 the operation of milk banks that handle and distribute donor

1 milk in this Commonwealth.

2 (b) Review of HMBANA guidelines.--The HMBANA guidelines
3 shall be reviewed every other year to determine if the current
4 guidelines maintain the necessary requirements and standards of
5 review for the operation and certification of milk banks in this
6 Commonwealth. After review, the department may continue to
7 accept the certification or develop the department's own
8 standards and requirements for licensure.

9 (c) Review of American Academy of Pediatrics guidelines.--
10 The department shall continually review the American Academy of
11 Pediatrics clinical guidelines on the assessment and
12 determination of medical necessity for the use of donor milk to
13 treat medically fragile infants and children.

14 (d) Application requirements.--The department shall develop
15 a standard written application for use by an entity applying to
16 operate a milk bank. The application shall at least include the
17 following:

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

19 (2) The name and address of the director and medical
20 director of the milk bank.

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

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

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

29 (6) Any other information required by the department.

30 (e) Inspection.--The department shall inspect each milk

1 bank's physical facilities and examine all required
2 documentation maintained by the milk bank prior to licensure and
3 at any time deemed necessary by the department.

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

6 (1) The name and address of the milk bank and each
7 affiliated satellite milk depot.

8 (2) The name and address of the director and medical
9 director of the milk bank.

10 (3) The signature of the Secretary of Health.

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

16 Section 8. Violations.

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

18 (1) The operation of a milk bank by an unlicensed
19 individual or entity.

20 (2) The direct or indirect sale of human milk by an
21 individual or entity not licensed under this act.

22 (3) Remuneration of value provided to milk donors.

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

25 Section 9. Exceptions.

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

30 (b) Availability of milk.--If facilitated by a milk bank

1 licensed under this act which lacks access to donor milk or a
2 specific type of milk ordered or prescribed to a Pennsylvania
3 resident, the milk may be procured from an out-of-State milk
4 bank which is approved by HMBANA or another nationally
5 recognized accrediting organization for the operation of milk
6 banks.

7 Section 10. Reports.

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

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

13 (i) The number of licensed milk banks in this
14 Commonwealth.

15 (ii) The address, including the county, for each
16 licensed milk bank.

17 (iii) A summary of the amount of milk donated,
18 processed and distributed by each milk bank organized by
19 facility type.

20 (iv) Any other information deemed necessary by the
21 department.

22 (2) The report shall be provided to:

23 (i) The chairperson and minority chairperson of the
24 Health and Human Services Committee of the Senate.

25 (ii) The chairperson and minority chairperson of the
26 Health Committee of the House of Representatives.

27 Section 11. Regulations.

28 (a) Application.--

29 (1) Upon the effective date of this subsection, the
30 department shall create an application for the licensure of

1 milk banks.

2 (2) The department shall begin accepting applications
3 for licensure of milk banks 120 days after the effective date
4 of this subsection.

5 (b) Regulations.--The department may promulgate rules and
6 regulations to administer and enforce this act.

7 Section 12. 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 (2) The remainder of this act shall take effect in 120
12 days.