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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 2516 Session of  
2018

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

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REFERRED TO COMMITTEE ON HEALTH, JUNE 19, 2018

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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  
16 receiving human milk.

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

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

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

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

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

5 Section 3. Definitions.

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

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

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

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

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

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

21 Section 4. Milk banks.

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

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

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

30 (2) The entity is:

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

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

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

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

11 (d) Denial.--

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

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

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

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

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

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

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

30 (g) Renewal.--A license issued under this act may be renewed

1 in accordance with the regulations promulgated by the department  
2 and upon the payment of a renewal fee.

3 (h) Suspension and revocation.--

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

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

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

16 Section 5. Operation of milk bank.

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

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

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

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

1 medical director and shall oversee the operation of the milk  
2 bank and develop governing policies.

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

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

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

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

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

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

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

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

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

30 (6) Refrigerating and freezer temperatures.

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

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

6 Section 6. Process of donation and distribution.

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

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

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

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

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

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

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

29           (iii) Has been exposed to possible environmental  
30 contaminants.

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

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

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

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

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

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

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

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

30          (7) Donor milk shall be shipped in clean, insulated



1 containers using packing material to minimize contamination  
2 of the outside of the bottles during transportation. Clean  
3 techniques shall be used to pack the milk in order to ensure  
4 the milk remains frozen.

5 (c) Storage.--Proper refrigeration and freezer capability  
6 shall be available at each milk bank, with appropriate  
7 thermometer calibration performed no less frequently than  
8 annually. The thermometer on each refrigerator and freezer used  
9 for the storage of donor milk shall be visually or mechanically  
10 monitored daily for possible fluctuations in temperature that  
11 could impact the quality of the donor milk.

12 Section 7. Duties of department.

13 (a) Oversight of milk banks.--The department shall regulate  
14 the operation of milk banks that handle and distribute donor  
15 milk in this Commonwealth.

16 (b) Review of HMBANA guidelines.--The HMBANA guidelines  
17 shall be reviewed every other year to determine if the current  
18 guidelines maintain the necessary requirements and standards of  
19 review for the operation and certification of milk banks in this  
20 Commonwealth. After review, the department may continue to  
21 accept the certification or develop the department's own  
22 standards and requirements for licensure.

23 (c) Review of American Academy of Pediatrics guidelines.--  
24 The department shall continually review the American Academy of  
25 Pediatrics clinical guidelines on the assessment and  
26 determination of medical necessity for the use of donor milk to  
27 treat medically fragile infants and children.

28 (d) Application requirements.--The department shall develop  
29 a standard written application for use by an entity applying to  
30 operate a milk bank. The application shall at least include the

1 following:

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

3 (2) The name and address of the director and medical  
4 director of the milk bank.

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

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

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

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

14 (e) Inspection.--The department shall inspect each milk  
15 bank's physical facilities and examine all required  
16 documentation maintained by the milk bank prior to licensure and  
17 at any time deemed necessary by the department.

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

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

22 (2) The name and address of the director and medical  
23 director of the milk bank.

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

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

30 Section 8. Violations.

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

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

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

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

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

9 Section 9. Exceptions.

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

14 (b) Availability of milk.--If facilitated by a milk bank  
15 licensed under this act which lacks access to donor milk or a  
16 specific type of milk ordered or prescribed to a Pennsylvania  
17 resident, the milk may be procured from an out-of-State milk  
18 bank which is approved by HMBANA or another nationally  
19 recognized accrediting organization for the operation of milk  
20 banks.

21 Section 10. 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. 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 licensure of milk banks 120 days after the effective date  
18 of this subsection.

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

21 Section 12. Effective date.

22 This act shall take effect as follows:

23 (1) This section and section 11 of this act shall take  
24 effect immediately.

25 (2) The remainder of this act shall take effect in 120  
26 days.