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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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**SENATE BILL**

No. **1263** Session of  
2018

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INTRODUCED BY BAKER, SCHWANK, BREWSTER, RAFFERTY, VULAKOVICH,  
WHITE, YUDICHAK, TARTAGLIONE, STEFANO, COSTA, BARTOLOTTA AND  
BLAKE, SEPTEMBER 25, 2018

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REFERRED TO HEALTH AND HUMAN SERVICES, SEPTEMBER 25, 2018

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AN ACT

1 Providing for licensure of milk banks; imposing powers and  
2 duties on the Department of Health; and prescribing  
3 penalties.

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

6 Section 1. Short title.

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

9 Section 2. Legislative intent.

10 The General Assembly finds and declares as follows:

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

14 (2) Medically vulnerable infants, such as those born  
15 prematurely, with low birth weight or congenital or acquired  
16 conditions, derive significant health benefits from receiving  
17 human milk.

18 (3) Necrotizing enterocolitis, a devastating and

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

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

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

17 (6) Children with a wide range of congenital or acquired  
18 conditions may benefit from the use of donor human milk as a  
19 component of treatment for their medical conditions.

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

24 (8) Banked donor milk is predominantly pasteurized to  
25 remove pathogens and frozen for storage and shipping.  
26 Volunteer donors are carefully screened and blood-tested to  
27 ensure that they are healthy and their milk is free from any  
28 chemical, disease or substance that could be injurious to  
29 high risk infants.

30 (9) The Human Milk Banking Association of North America

1 (HMBANA) is a professional association that establishes and  
2 maintains current, rigorous guidelines for the operation of  
3 human milk banks throughout North America.

4 Section 3. Definitions.

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

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

10 "American Academy of Pediatrics" or "(AAP)." An American  
11 professional association of pediatricians that issues clinical  
12 guidelines governing the use of donor milk in the delivery of  
13 medically necessary care to newborns and babies.

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

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

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

23 "Committee." The medical advisory committee formed by a milk  
24 bank in accordance with section 5(a)(3).

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

26 "Dispensary." A center that has an agreement with a milk  
27 bank for the distribution of milk from the milk bank by  
28 prescription.

29 "Distribution." The delivery of medically ordered or  
30 prescribed donor milk to an acute care hospital, birth center,

1 lactation center, pharmacy, dispensary or medically approved  
2 outpatient by a milk bank licensed in this Commonwealth.

3 "Donor." A lactating woman with an excess supply of human  
4 milk, who voluntarily contributes milk to a milk bank after  
5 being medically screened and approved for milk donation and who  
6 receives no remuneration for the donation of milk.

7 "Donor milk." Human milk derived from a properly screened  
8 donor that is voluntarily donated to a milk bank and processed  
9 for distribution.

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

12 "License." A license issued by the department under this  
13 act.

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

20 "Licensee." A milk bank that holds a valid license under the  
21 provisions of this act.

22 "Milk bank." An entity that collects donor milk from  
23 volunteer medically screened human donors and distributes the  
24 donor milk to medically fragile children other than the donor's  
25 own child based on a healthcare provider's order or  
26 prescription, using storage, processing and shipping methods  
27 required by the department.

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

30 "Person." A natural person, partnership, association,

1 corporation, institution, agency or other similar type entity.

2 "Pharmacy." A store where medicinal drugs are dispensed and  
3 sold.

4 "Processing." The standards and techniques approved by the  
5 department for removing pathogens from donor milk and ensuring  
6 its safety.

7 "Professional association." A professional association that  
8 establishes and requires member compliance with guidelines for  
9 the operation of human milk banks throughout North America. The  
10 term includes, but is not limited to, HMBANA.

11 "Professional association guidelines." Guidelines issued by  
12 a professional association that govern the operation of milk  
13 banks in the United States.

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

17 "Screening of donors" or "donor screening process." The  
18 process of evaluating prospective volunteer donors by a milk  
19 bank to determine the acceptability of the donor milk based on  
20 past medical history, medication use, present state of health  
21 and indicated laboratory studies and which process has been  
22 approved prior to implementation by the department.

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

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

27 Section 4. Licensure of milk banks.

28 (a) General rule.--A milk bank operating or seeking to  
29 operate in this Commonwealth must apply to the department and  
30 obtain a license. The department shall issue a license to a milk

1 bank that is certified as a member in good standing by a  
2 professional association subject to the review and approval  
3 process specified in section 6(c) or that is otherwise in  
4 compliance with the requirements of this act.

5 (b) Suspension or revocation of license.--The department may  
6 suspend or revoke a license issued under subsection (a) for  
7 noncompliance with the provisions of this act.

8 Section 5. Administration of milk banks.

9 (a) Licensee requirements.--

10 (1) A licensee shall develop and ensure the  
11 implementation of policies and procedures consistent with  
12 professional association guidelines or the requirements of  
13 this act.

14 (2) A licensee shall appoint a person to serve as the  
15 chief operating officer of the licensee. The chief operating  
16 officer shall be responsible for the day-to-day operation of  
17 the licensee.

18 (3) A licensee shall be managed by a board of directors  
19 or similar body. Among other responsibilities, the board of  
20 directors shall be responsible for the appointment of the  
21 chief operating officer, a medical director and a medical  
22 advisory committee.

23 (4) The medical director must be a licensed physician  
24 with a minimum of four years' experience in neonatology,  
25 pediatrics, blood banking or a related field. The medical  
26 director shall serve as a member of the board of directors of  
27 the licensee.

28 (5) The medical advisory committee shall be composed of  
29 physicians and other allied health personnel with experience  
30 in neonatology, blood banking, nutrition and other related

1 expertise. At least one member of the medical advisory  
2 committee must have expertise in infectious diseases.

3 (b) Donor qualifications.--

4 (1) A person who volunteers to provide donor milk shall  
5 successfully complete the donor screening process.

6 (2) In addition to any other provisions of the donor  
7 screening process, the following shall apply:

8 (i) A donor shall authorize a milk bank to contact  
9 both her health care provider and the health care  
10 provider for the donor's baby so that the donor and the  
11 donor's baby may be medically screened and blood-tested  
12 to ensure the health of the potential donor and her baby  
13 and to ensure that the donor milk is free from any  
14 chemical, disease or substance that could be injurious to  
15 an infant receiving it.

16 (ii) A person who is at high risk for bloodborne  
17 pathogens or other acute and chronic infectious diseases  
18 shall be excluded from serving as a donor.

19 (iii) Donations may be precluded for:

20 (A) Use of medications not approved by the  
21 department, tobacco, alcohol or other substances  
22 identified by the department.

23 (B) Systemic chronic diseases or nutritional  
24 deficiencies.

25 (C) Exposure to possible environmental  
26 contaminants.

27 (D) The inability or failure to follow  
28 directions regarding sanitary collection and storage  
29 of donor milk or other relevant contraindications to  
30 donation established by the department.

1 (c) Donor milk processing.--A licensee shall comply with all  
2 of the following requirements for donor milk processing:

3 (1) Pasteurization or processing methods approved by the  
4 department shall be used to remove pathogens from donor milk,  
5 including the Holder pasteurization method.

6 (2) Post-pasteurization bacteriologic cultures shall be  
7 performed.

8 (3) Containers holding unprocessed donor milk shall be  
9 labeled with the donor's identification number and collection  
10 date. Unprocessed donor milk stored at a satellite milk depot  
11 shall be labeled with the location of the milk depot and the  
12 date and time of receipt by the milk depot and, after  
13 transport of the milk to the milk bank, the date of such  
14 transport.

15 (4) Processed milk shall be documented and packaged in  
16 Bisphenol-A and phthalate-free containers that are FDA-  
17 approved food safe vessels for heating and freezing. Each  
18 container shall be labeled with the expiration date, batch  
19 number and licensee name. Labeling shall be compatible with  
20 hospital donor milk inventory and feeding systems, as  
21 appropriate.

22 (5) Donor milk shall be stored and transported at a  
23 temperature safe from contamination, thawing and refreezing.

24 (6) Donor milk shall be shipped in clean, insulated  
25 containers and packed to minimize contamination of the  
26 outside of the bottle during transport. Techniques shall be  
27 used in packing to ensure the product remains frozen.

28 (d) Donor milk storage.--

29 (1) Proper refrigeration and freezer capability shall be  
30 used by a licensee, with thermometer calibration performed at

1 least annually.

2 (2) Refrigerators and freezers used to store donor milk  
3 shall be visually or mechanically monitored daily for  
4 temperature fluctuations that could affect the donor milk  
5 quality.

6 (e) Maintenance of records.--A licensee shall maintain the  
7 information required under this subsection in a manner  
8 determined by the department for inspection:

9 (1) An individual file for each milk donor, including  
10 the donor's consent for participation in the milk bank  
11 program and the results of all clinical laboratory tests  
12 performed prior to approval as a donor and during  
13 participation in the program. Information that would directly  
14 or indirectly identify the donor may not be disclosed by the  
15 licensee to any person, other than authorized agents of the  
16 department, without the written consent of the donor.

17 (2) Records of milk donation filed by donor  
18 identification number, including information from container  
19 identification tags as provided by subsection (c). All  
20 distributed milk shall be capable of being traced back to the  
21 individual donors.

22 (3) The pasteurization date of the donor milk and the  
23 date the donor milk was distributed or used. Identifying  
24 information for donor milk pooled from multiple donors shall  
25 be separately recorded and maintained by the donor.

26 (4) Bacteriological testing results and dates for each  
27 batch of donor milk.

28 (5) Tracking and shipment information regarding the  
29 distribution of donor milk by facility or specific outpatient  
30 use.

1 (6) Refrigeration and freezer temperature records for at  
2 least one year after distribution or disposal by the  
3 licensee.

4 (7) Licensee operating policies and procedures.

5 (f) Submission of professional association accreditation.--

6 (1) A licensee shall submit professional association  
7 certification information to the department within 30 days of  
8 each professional association inspection and accreditation of  
9 the licensee, as applicable.

10 (2) A licensee shall notify the department within 72  
11 hours when membership in a professional association is  
12 terminated for any reason.

13 (g) Display of license.--A licensee shall display the  
14 license in a prominent place at the main facility of the  
15 licensee.

16 (h) Disclosure of relationships.--A licensee shall notify  
17 the department within seven days of establishing a relationship  
18 with a dispensary or satellite milk depot.

19 Section 6. Duties of department.

20 (a) General rule.--The department shall regulate the  
21 operation of licensees that handle and distribute donor milk in  
22 this Commonwealth.

23 (b) License required.--The department shall issue licenses  
24 in accordance with the requirements of this act.

25 (c) Review of professional association guidelines.--

26 (1) The department shall review and approve professional  
27 association guidelines to ensure that the guidelines in use  
28 maintain the necessary requirements and standards of review  
29 for the safe operation and certification of licensees in this  
30 Commonwealth. If, at any time, the department determines that

1 the guidelines in use by the professional association do not  
2 maintain necessary requirements and standards of review for  
3 the safe operation and certification of licensees, licensees  
4 must satisfy the requirements provided for in paragraph (2).

5 (2) The department shall adopt standards and  
6 requirements for licensure separate from those of the  
7 professional association guidelines referenced in paragraph  
8 (1) which the department determines are sufficient to  
9 maintain the safe operation and certification of licensees.

10 (3) Licensees may satisfy either the standards and  
11 requirements established by the department or the standards  
12 of the professional association referenced in paragraph (1).

13 (d) Application requirements.--The department shall develop  
14 a standard written application for a license, which shall  
15 provide for all of the following:

16 (1) The name and location of the applicant.

17 (2) The name and address of the chief operating officer  
18 and medical director of the applicant.

19 (3) The education and experience history of all persons  
20 having supervisory or technical duties related to the  
21 operation of the applicant.

22 (4) A description of the physical facilities, location,  
23 equipment, sources of materials and methods of processing,  
24 storage and distribution of donor milk.

25 (5) A description of all technical procedures used in  
26 the routine operations of the applicant.

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

29 (7) Such additional information as the department may  
30 require.

1 (e) Inspection.--

2 (1) Prior to issuing a license to an applicant, the  
3 department shall inspect the applicant's physical facilities  
4 and, at the department's discretion, the physical facilities  
5 of any dispensary or milk depot with which the licensee has a  
6 relationship, shall examine all required documentation.

7 (2) The department may subsequently inspect a licensee  
8 at any time deemed appropriate by the department upon  
9 reasonable notice.

10 (f) Issuance of license.--

11 (1) The department shall issue a license if the  
12 department is satisfied that the applicant has complied with  
13 the provisions of this act and applicable rules and  
14 regulations adopted by the department.

15 (2) A milk bank in operation prior to the effective date  
16 of this section may continue to operate pending a decision on  
17 its application if an application is made within 120 days of  
18 the later of the effective date of this section or the date  
19 that an application for a license is first made available to  
20 prospective licensees pursuant to this act.

21 (g) Expiration of license.--A license shall expire two years  
22 after the date of issuance unless renewed. A license may be  
23 renewed in the same manner as the issuance of the original  
24 license and upon payment of a renewal application fee as  
25 specified in section 7.

26 (h) Contents and signing of license.--A license issued by  
27 the department shall include:

28 (1) The name and address of the licensee and the  
29 location of all facilities, dispensaries and affiliated  
30 satellite milk depots authorized under the license.

1           (2) The name and address of the chief operating officer  
2           and medical director.

3           (3) The signature of the secretary.

4           (i) Statement of grounds for denial of license.--If the  
5           department does not issue a license to an applicant within six  
6           months after the filing of an application, the license shall be  
7           deemed denied. When an application is denied or deemed denied,  
8           the department shall, within seven days, state the grounds and  
9           reason for its refusal, in writing, with a copy to the  
10          applicant.

11          (j) Hearings and appeals.--If an applicant is denied a  
12          license, the applicant may request and receive a hearing before  
13          the secretary, if the hearing request is made within 30 days  
14          after receiving notice of denial.

15          (k) Revocation of license.--

16                 (1) A license may be suspended or revoked by the  
17                 department for a violation of any provision of this act.

18                 (2) Before the department suspends or revokes a license,  
19                 written notification shall be provided to the licensee. The  
20                 notification shall specify the reason for revocation or  
21                 suspension and indicate a time and place for a hearing on the  
22                 matter, to be held within 30 days of notification.

23          (l) Ongoing review.--The department shall conduct an ongoing  
24          review of the clinical guidelines issued by the American Academy  
25          of Pediatrics regarding the assessment and determination of  
26          medical necessity for the use of donor milk to treat medically  
27          fragile infants and children.

## 28 Section 7. Licensure fees.

29          In order to obtain licensure by the department, an applicant  
30          shall submit an initial licensure fee of \$1,000, with a \$250 fee

1 for each renewal thereafter. All money derived from the payment  
2 of licensure fees under this act shall be used for the  
3 administration of this act.

4 Section 8. Exceptions.

5 (a) General rule.--A milk bank located in this Commonwealth  
6 and otherwise regulated by the department through its hospital  
7 licensure process shall not be subject to the requirements of  
8 this act, provided the milk bank's distribution of donor milk is  
9 confined to the hospital and the outpatients of the hospital.

10 (b) Milk banks outside this Commonwealth.--In the event a  
11 licensee lacks access to donor milk or a specific type of donor  
12 milk prescribed to an individual residing in this Commonwealth,  
13 a milk bank located outside of Pennsylvania that is a member of  
14 a professional association may distribute donor milk within this  
15 Commonwealth at the specific direction and in accordance with  
16 the instructions of a licensee.

17 Section 9. Prohibitions and penalty.

18 (a) License required.--No person may operate a milk bank in  
19 this Commonwealth unless licensed by the department in  
20 accordance with the provisions of this act.

21 (b) Prohibited practices.--The following practices shall be  
22 prohibited in this Commonwealth:

23 (1) The direct or indirect sale of donor milk for profit  
24 by an entity not licensed in this Commonwealth.

25 (2) Monetary remuneration or any other remuneration of  
26 value provided to an individual for the donation of donor  
27 milk.

28 (c) Penalties.--

29 (1) A violation of subsection (b)(1) shall be a  
30 misdemeanor of the third degree.

1           (2) A violation of subsection (b)(2) shall be a summary  
2       offense.

3 Section 10. Biennial report.

4       (a) Duty to prepare and file.--The department shall prepare  
5 a biennial report by July 1 in odd-numbered years regarding the  
6 operation of milk banks in this Commonwealth. The report shall  
7 be filed with the chairman and minority chairman of the Health  
8 and Human Services Committee of the Senate and the chairman and  
9 minority chairman of the Health Committee of the House of  
10 Representatives.

11       (b) Contents.--The report shall include:

12           (1) The number, location and county of licensees.

13           (2) A summary of the amount of donor milk donated,  
14       processed and distributed by each licensee by type of medical  
15       facility.

16           (3) Any other information the department may deem  
17       necessary.

18 Section 11. Regulations.

19       The department may promulgate regulations for the  
20 implementation of this act.

21 Section 12. Effective date.

22       This act shall take effect in 120 days.