



**FLOOR AMENDMENT STATEMENT:** No

**LEGISLATIVE FISCAL ESTIMATE:** Yes

**VETO MESSAGE:** No

**GOVERNOR'S PRESS RELEASE ON SIGNING:** No

**FOLLOWING WERE PRINTED:**

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or <mailto:refdesk@njstatelib.org>

**REPORTS:** No

**HEARINGS:** No

**NEWSPAPER ARTICLES:** Yes

"Outgoing governor approves array of healthcare programs," NJ Spotlight, January 9, 2017

RWH/CL

Title 26.  
Chapter 2A  
(Rename)  
Human Biological  
Materials  
§§ 1-6 -  
C.26:2A-17 to  
26:2A-22  
§7 - Note

P.L.2017, CHAPTER 247, *approved January 8, 2018*  
Senate, No. 974 (*First Reprint*)

1 AN ACT concerning human milk banks and supplementing Title 26  
2 of the Revised Statutes.

3  
4 **BE IT ENACTED** by the Senate and General Assembly of the State  
5 of New Jersey:

6  
7 1. For the purposes of this act:

8 "Collection" means the obtaining of donated human breast milk.

9 "Commissioner" means the Commissioner of Health.

10 "Department" means the Department of Health.

11 "Distribution" means the removal of donated human breast milk  
12 from a human milk bank to any other location for processing or  
13 storage or for the purpose of providing breast milk to a hospital or  
14 selling breast milk to a parent.

15 "Human milk bank" means an organized service that provides for  
16 the selection of a donor of human breast milk, the collection,  
17 processing, storage, and marketing of donated human breast milk,  
18 and the distribution of donated human breast milk to a hospital for  
19 use by low birth weight babies or new mothers with delayed  
20 lactation, or directly to a parent, with a physician's prescription  
21 order, who is unable to nurse, or is in need of additional breast milk  
22 to feed, the parent's child.

23 "Marketing" means the use of suitable media to advertise the  
24 availability of, promote the appropriate use of, and provide  
25 information on how to safely procure, donated human breast milk.

26 "Person" means a person, partnership, association, agency,  
27 organization, or other similar entity.

28 "Processing" means the technical stages required to prepare and  
29 identify donated human breast milk as to its suitability.

30 "Storage" means the holding of donated human breast milk in  
31 connection with collection or processing prior to its distribution.

**EXPLANATION** – Matter enclosed in bold-faced brackets **[thus]** in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

<sup>1</sup>Senate floor amendments adopted January 23, 2017.

1       2. a. A person shall not operate a human milk bank that is  
2 located in this State or distributes donated human milk in this State  
3 unless the human milk bank is <sup>1</sup>an accredited member of the  
4 Human Milk Bank Association of North America, or the  
5 accreditation agency selected by the department pursuant to  
6 subsection c. of this section, as applicable] accredited by<sup>1</sup>, and  
7 registered with <sup>1</sup><sub>2</sub> the department pursuant to this act.

8       b. Any person desiring to operate a human milk bank shall:

9       (1) adhere to the guidelines for the establishment and operation  
10 of a donor human milk bank as required by <sup>1</sup>the Human Milk Bank  
11 Association of North America, or the accreditation agency selected  
12 by] <sup>1</sup> the department <sup>1</sup>pursuant to subsection c. of this section, as  
13 applicable] <sup>1</sup>;

14       (2) adhere to the best practices for expressing, storing, and  
15 handling human milk in hospitals, homes, and child care settings as  
16 required by <sup>1</sup>the Human Milk Bank Association of North America,  
17 or the accreditation agency selected by] <sup>1</sup> the department <sup>1</sup>pursuant  
18 to subsection c. of this section, as applicable] <sup>1</sup>;

19       (3) undergo a yearly assessment by <sup>1</sup>the Human Milk Bank  
20 Association of North America, or the accreditation agency selected  
21 by] <sup>1</sup> the department <sup>1</sup>pursuant to subsection c. of this section, as  
22 applicable] <sup>1</sup>, to provide evidence of adherence to the most recent  
23 edition of guidelines for the establishment and operation of a  
24 <sup>1</sup>donor] <sup>1</sup> human milk bank;

25       (4) comply with any <sup>1</sup>other<sup>1</sup> provisions required by <sup>1</sup>the  
26 Human Milk Bank Association of North America, or the  
27 accreditation agency selected by] <sup>1</sup> the department <sup>1</sup>pursuant to  
28 subsection c. of this section, as applicable] <sup>1</sup>;

29       (5) register with the department in a form and manner  
30 prescribed by the department; and

31       (6) pay to the department an annual registration fee established  
32 by the department in order to offset the department's administrative  
33 costs incurred in executing its responsibilities under this act.

34       <sup>1</sup>c. The department shall, five years after the effective date of  
35 this act and every five years thereafter, conduct a review to  
36 determine whether the Human Milk Bank Association of North  
37 America continues to be the most appropriate accreditation  
38 authority for human milk banks and that its guidelines are proper  
39 and sufficient. Upon the completion of a review, the commissioner  
40 may, by regulations adopted pursuant to the "Administrative  
41 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), change the  
42 accreditation authority.] <sup>1</sup>

43  
44       3. The department shall conduct an on-site facility inspection  
45 of each registered human milk bank at least once every five years  
46 <sup>1</sup><sub>2</sub> and shall inspect documents, records, files, or other data

1 maintained by a human milk bank during normal operating hours  
2 and without prior notice. If the department's inspection finds that a  
3 human milk bank is not in compliance with the 'department's'  
4 requirements and guidelines '[of the Human Milk Bank  
5 Association of North America, or the accreditation agency selected  
6 by the department pursuant to subsection c. of section 2 of this act,  
7 as applicable, ]' for 'the' accreditation of human milk banks, the  
8 department shall '[notify the agency that it does not believe the  
9 bank qualifies for accreditation ]' revoke the human milk bank's  
10 accreditation'.  
11

12 4. a. The commissioner is authorized to institute a civil action  
13 in a court of competent jurisdiction for injunctive relief to enjoin  
14 the operation of a human milk bank whenever the commissioner  
15 determines that:

16 (1) a condition exists or has occurred at the human milk bank  
17 that is dangerous to the public health;

18 (2) the human milk bank has repeatedly violated the provisions  
19 of this act; or

20 (3) a human milk bank has opened or is operating without  
21 complying with the provisions of this act.

22 b. The commissioner may, in addition, request such other relief  
23 as is deemed necessary. In any such action the court may proceed  
24 in a summary manner.

25 c. Any person aggrieved by a final decision of the  
26 commissioner shall be entitled to seek judicial review in the  
27 Appellate Division of the Superior Court. All petitions for review  
28 shall be filed in accordance with the Rules of the Court.  
29

30 5. a. Any person who operates a human milk bank that is not  
31 accredited and registered pursuant to this act, or who has used fraud  
32 or misrepresentation in obtaining accreditation or registration or in  
33 the subsequent operation of a human milk bank, or who violates any  
34 other provision of this act shall be subject to a penalty of not less  
35 than \$100 or more than \$1,000 for the first offense and not less than  
36 \$500 or more than \$5,000 for the second or any subsequent offense.

37 b. The department shall have the jurisdiction to enforce and  
38 collect any penalty imposed because of a violation of this act in a  
39 summary proceeding in accordance with the "Penalty Enforcement  
40 Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). Process shall  
41 be in the nature of a summons or warrant and shall issue only at the  
42 suit of the commissioner as plaintiff.

43 c. A penalty recovered pursuant to the provisions of this  
44 section shall be recovered by the commissioner and paid into the  
45 State treasury.  
46

47 6. The commissioner, pursuant to the "Administrative  
48 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt

1 rules and regulations necessary to effectuate the purposes of this  
2 act.

3

4 7. This act shall take effect on the 180th day after the date of  
5 enactment but the commissioner may take such anticipatory  
6 administrative action in advance thereof as shall be necessary for  
7 the implementation of this act.

8

9

10

11

12 Provides for registration and accreditation of human milk banks.

[Corrected Copy]

**SENATE, No. 974**

**STATE OF NEW JERSEY**  
**217th LEGISLATURE**

INTRODUCED FEBRUARY 4, 2016

**Sponsored by:**

**Senator LORETTA WEINBERG**

**District 37 (Bergen)**

**Senator NILSA CRUZ-PEREZ**

**District 5 (Camden and Gloucester)**

**Co-Sponsored by:**

**Senator Stack**

**SYNOPSIS**

Provides for registration and accreditation of human milk banks.

**CURRENT VERSION OF TEXT**

As introduced.



**(Sponsorship Updated As Of: 11/15/2016)**

1 AN ACT concerning human milk banks and supplementing Title 26  
2 of the Revised Statutes.

3

4 **BE IT ENACTED** by the Senate and General Assembly of the State  
5 of New Jersey:

6

7 1. For the purposes of this act:

8 "Collection" means the obtaining of donated human breast milk.

9 "Commissioner" means the Commissioner of Health.

10 "Department" means the Department of Health.

11 "Distribution" means the removal of donated human breast milk  
12 from a human milk bank to any other location for processing or  
13 storage or for the purpose of providing breast milk to a hospital or  
14 selling breast milk to a parent.

15 "Human milk bank" means an organized service that provides for  
16 the selection of a donor of human breast milk, the collection,  
17 processing, storage, and marketing of donated human breast milk,  
18 and the distribution of donated human breast milk to a hospital for  
19 use by low birth weight babies or new mothers with delayed  
20 lactation, or directly to a parent, with a physician's prescription  
21 order, who is unable to nurse, or is in need of additional breast milk  
22 to feed, the parent's child.

23 "Marketing" means the use of suitable media to advertise the  
24 availability of, promote the appropriate use of, and provide  
25 information on how to safely procure, donated human breast milk.

26 "Person" means a person, partnership, association, agency,  
27 organization, or other similar entity.

28 "Processing" means the technical stages required to prepare and  
29 identify donated human breast milk as to its suitability.

30 "Storage" means the holding of donated human breast milk in  
31 connection with collection or processing prior to its distribution.

32

33 2. a. A person shall not operate a human milk bank that is  
34 located in this State or distributes donated human milk in this State  
35 unless the human milk bank is an accredited member of the Human  
36 Milk Bank Association of North America, or the accreditation  
37 agency selected by the department pursuant to subsection c. of this  
38 section, as applicable, and registered with the department pursuant  
39 to this act.

40 b. Any person desiring to operate a human milk bank shall:

41 (1) adhere to the guidelines for the establishment and operation  
42 of a donor human milk bank as required by the Human Milk Bank  
43 Association of North America, or the accreditation agency selected  
44 by the department pursuant to subsection c. of this section, as  
45 applicable;

46 (2) adhere to the best practices for expressing, storing, and  
47 handling human milk in hospitals, homes, and child care settings as  
48 required by the Human Milk Bank Association of North America,



1 or the accreditation agency selected by the department pursuant to  
2 subsection c. of this section, as applicable;

3 (3) undergo a yearly assessment by the Human Milk Bank  
4 Association of North America, or the accreditation agency selected  
5 by the department pursuant to subsection c. of this section, as  
6 applicable, to provide evidence of adherence to the most recent  
7 edition of guidelines for the establishment and operation of a donor  
8 human milk bank;

9 (4) comply with any provisions required by the Human Milk  
10 Bank Association of North America, or the accreditation agency  
11 selected by the department pursuant to subsection c. of this section,  
12 as applicable;

13 (5) register with the department in a form and manner  
14 prescribed by the department; and

15 (6) pay to the department an annual registration fee established  
16 by the department in order to offset the department's administrative  
17 costs incurred in executing its responsibilities under this act.

18 c. The department shall, five years after the effective date of  
19 this act and every five years thereafter, conduct a review to  
20 determine whether the Human Milk Bank Association of North  
21 America continues to be the most appropriate accreditation  
22 authority for human milk banks and that its guidelines are proper  
23 and sufficient. Upon the completion of a review, the commissioner  
24 may, by regulations adopted pursuant to the "Administrative  
25 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), change the  
26 accreditation authority.

27  
28 3. The department shall conduct an on-site facility inspection  
29 of each registered human milk bank at least once every five years  
30 and shall inspect documents, records, files, or other data maintained  
31 by a human milk bank during normal operating hours and without  
32 prior notice. If the department's inspection finds that a human milk  
33 bank is not in compliance with the requirements and guidelines of  
34 the Human Milk Bank Association of North America, or the  
35 accreditation agency selected by the department pursuant to  
36 subsection c. of section 2 of this act, as applicable, for accreditation  
37 of human milk banks, the department shall notify the agency that it  
38 does not believe the bank qualifies for accreditation.

39  
40 4. a. The commissioner is authorized to institute a civil action  
41 in a court of competent jurisdiction for injunctive relief to enjoin  
42 the operation of a human milk bank whenever the commissioner  
43 determines that:

44 (1) a condition exists or has occurred at the human milk bank  
45 that is dangerous to the public health;

46 (2) the human milk bank has repeatedly violated the provisions  
47 of this act; or

1 (3) a human milk bank has opened or is operating without  
2 complying with the provisions of this act.

3 b. The commissioner may, in addition, request such other relief  
4 as is deemed necessary. In any such action the court may proceed  
5 in a summary manner.

6 c. Any person aggrieved by a final decision of the  
7 commissioner shall be entitled to seek judicial review in the  
8 Appellate Division of the Superior Court. All petitions for review  
9 shall be filed in accordance with the Rules of the Court.

10

11 5. a. Any person who operates a human milk bank that is not  
12 accredited and registered pursuant to this act, or who has used fraud  
13 or misrepresentation in obtaining accreditation or registration or in  
14 the subsequent operation of a human milk bank, or who violates any  
15 other provision of this act shall be subject to a penalty of not less  
16 than \$100 or more than \$1,000 for the first offense and not less than  
17 \$500 or more than \$5,000 for the second or any subsequent offense.

18 b. The department shall have the jurisdiction to enforce and  
19 collect any penalty imposed because of a violation of this act in a  
20 summary proceeding in accordance with the "Penalty Enforcement  
21 Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). Process shall  
22 be in the nature of a summons or warrant and shall issue only at the  
23 suit of the commissioner as plaintiff.

24 c. A penalty recovered pursuant to the provisions of this  
25 section shall be recovered by the commissioner and paid into the  
26 State treasury.

27

28 6. The commissioner, pursuant to the "Administrative  
29 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt  
30 rules and regulations necessary to effectuate the purposes of this  
31 act.

32

33 7. This act shall take effect on the 180th day after the date of  
34 enactment but the commissioner may take such anticipatory  
35 administrative action in advance thereof as shall be necessary for  
36 the implementation of this act.

37

38

39

#### STATEMENT

40

41 This bill provides for the registration and accreditation of human  
42 milk banks. As defined in the bill, "human milk bank" means an  
43 organized service that provides for the selection of a donor of  
44 human breast milk and the collection, processing, storage, and  
45 marketing of human breast milk, and the distribution of donated  
46 human breast milk to a hospital for use by low birth weight babies  
47 or new mothers with delayed lactation, or directly to a parent, with

1 a physician's prescription order, who is unable to nurse, or is in  
2 need of additional breast milk to feed the parent's child.

3 Specifically, the bill requires that a person (a person, partnership,  
4 association, agency, organization, or other similar type entity) be an  
5 accredited member of the Human Milk Bank Association of North  
6 America, or a successor accreditation agency selected by the  
7 Department of Health (DOH), and registered with the DOH.

8 Under the provisions of the bill, a person desiring to operate a  
9 human milk bank must:

- 10 • adhere to the guidelines for the establishment and operation  
11 of a donor human milk bank as required by the Human Milk  
12 Bank Association of North America or successor  
13 accreditation agency;
- 14 • adhere to the best practices for expressing, storing, and  
15 handling human milk in hospitals, homes, and child care  
16 settings as required by the Human Milk Bank Association of  
17 North America or successor accreditation agency;
- 18 • undergo a yearly assessment by the Human Milk Bank  
19 Association of North America or successor accreditation  
20 agency, to provide evidence of adherence to the most recent  
21 edition of guidelines for the establishment and operation of a  
22 donor human milk bank;
- 23 • comply with any provisions required by the Human Milk  
24 Bank Association of North America or successor  
25 accreditation agency;
- 26 • register with the DOH in a form and manner prescribed by  
27 the department; and
- 28 • pay to the DOH an annual registration fee established by the  
29 DOH in order to offset the DOH's administrative costs.

30  
31 The bill also requires DOH to conduct an on-site facility  
32 inspection of a human milk bank at least once every five years. The  
33 inspection would include an inspection of records, files, and other  
34 data. If the DOH finds that a registered milk bank is not in  
35 compliance with accreditation requirements, it would notify the  
36 accreditation agency that it does not believe the milk bank qualifies  
37 for accreditation.

38 The bill gives the commissioner of DOH the authority to institute  
39 a civil action to enjoin the operation of a human milk bank  
40 whenever the commissioner determines that: a condition exists or  
41 has occurred at the human milk bank that is dangerous to the public  
42 health; a milk bank has repeatedly violated the provisions of the  
43 bill; or a milk bank has opened or is operating without complying  
44 with the provisions of the bill.

45 The commissioner could also request other relief, and in any  
46 action, the court would proceed in a summary manner. Any person  
47 aggrieved by a final decision of the commissioner would be entitled  
48 to seek judicial review.

1       Finally, the bill stipulates that any person who: operates a human  
2 milk bank that is not accredited and registered pursuant to the bill;  
3 or who has used fraud or misrepresentation in obtaining a license or  
4 in the subsequent operation of a human milk bank; or violates any  
5 other provision of the bill would be subject to a penalty of not less  
6 than \$100 or than \$1,000 for the first offense and not less than \$500  
7 or no than \$5,000 for the second or any subsequent offense. DOH  
8 would enforce and collect any penalty imposed in accordance with  
9 the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-  
10 10 et seq.). The penalty would be recovered by the commissioner  
11 and paid into the State treasury.

SENATE HEALTH, HUMAN SERVICES AND SENIOR  
CITIZENS COMMITTEE

STATEMENT TO

**SENATE, No. 974**

**STATE OF NEW JERSEY**

DATED: FEBRUARY 4, 2016

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 974.

This bill provides for the registration and accreditation of human milk banks. As defined in the bill, "human milk bank" means an organized service that provides for the selection of a donor of human breast milk and the collection, processing, storage, and marketing of human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed the parent's child.

Specifically, the bill requires that a person (a person, partnership, association, agency, organization, or other similar type entity) be an accredited member of the Human Milk Bank Association of North America, or a successor accreditation agency selected by the Department of Health (DOH), and registered with the DOH.

Under the provisions of the bill, a person desiring to operate a human milk bank must:

- adhere to the guidelines for the establishment and operation of a donor human milk bank as required by the Human Milk Bank Association of North America or successor accreditation agency;
- adhere to the best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings as required by the Human Milk Bank Association of North America or successor accreditation agency;
- undergo a yearly assessment by the Human Milk Bank Association of North America or successor accreditation agency, to provide evidence of adherence to the most recent edition of guidelines for the establishment and operation of a donor human milk bank;
- comply with any provisions required by the Human Milk Bank Association of North America or successor accreditation agency;

- register with the DOH in a form and manner prescribed by the department; and
- pay to the DOH an annual registration fee established by the DOH in order to offset the DOH's administrative costs.

The bill also requires DOH to conduct an on-site facility inspection of a human milk bank at least once every five years. The inspection would include an inspection of records, files, and other data. If the DOH finds that a registered milk bank is not in compliance with accreditation requirements, it would notify the accreditation agency that it does not believe the milk bank qualifies for accreditation.

The bill gives the commissioner of DOH the authority to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the bill; or a milk bank has opened or is operating without complying with the provisions of the bill.

The commissioner could also request other relief, and in any action, the court would proceed in a summary manner. Any person aggrieved by a final decision of the commissioner would be entitled to seek judicial review.

Finally, the bill stipulates that any person who: operates a human milk bank that is not accredited and registered pursuant to the bill; or who has used fraud or misrepresentation in obtaining a license or in the subsequent operation of a human milk bank; or violates any other provision of the bill would be subject to a penalty of not less than \$100 or than \$1,000 for the first offense and not less than \$500 or no than \$5,000 for the second or any subsequent offense. DOH would enforce and collect any penalty imposed in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). The penalty would be recovered by the commissioner and paid into the State treasury.

# SENATE BUDGET AND APPROPRIATIONS COMMITTEE

## STATEMENT TO

[Corrected Copy]  
**SENATE, No. 974**

# STATE OF NEW JERSEY

DATED: NOVEMBER 3, 2016

The Senate Budget and Appropriations Committee reports favorably Senate Bill No. 974.

This bill provides for the registration and accreditation of human milk banks. As defined by the bill, a “human milk bank” is an organized service that provides for the selection of a donor of human breast milk, the collection, processing, storage, and marketing of human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed the parent's child.

The bill specifically prohibits a person from operating a human milk bank that is located in this State or from distributing donated human milk in this State unless the human milk bank is an accredited member of the Human Milk Bank Association of North America, or a successor accreditation agency selected by the Department of Health, and is registered with the department.

Under the bill, a person desiring to operate a human milk bank must:

- adhere to the guidelines for the establishment and operation of a donor human milk bank as required by the Human Milk Bank Association of North America or successor accreditation agency;

- adhere to the best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings as required by the Human Milk Bank Association of North America or successor accreditation agency;

- undergo a yearly assessment by the Human Milk Bank Association of North America or successor accreditation agency, to provide evidence of adherence to the most recent edition of guidelines for the establishment and operation of a donor human milk bank;

- comply with any provisions required by the Human Milk Bank Association of North America or successor accreditation agency;

- register with the department in a form and manner prescribed by the department; and

-- pay an annual registration fee established by the department to offset the department's administrative costs.

The bill requires the department to conduct an on-site facility inspection of a human milk bank at least once every five years. The inspection is to include an inspection of records, files, and other data maintained by a human milk bank. If the department finds that a registered human milk bank is not in compliance with accreditation requirements, the department is to notify the accreditation agency that it does not believe the human milk bank qualifies for accreditation.

The bill authorizes the Commissioner of Health to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the bill; or a milk bank has opened or is operating without complying with the provisions of the bill. The bill permits the commissioner to request other relief as is deemed necessary, and provides that in any such action, the court may proceed in a summary manner. Any person aggrieved by a final decision of the commissioner is entitled to seek judicial review in the Appellate Division of the Superior Court.

The bill provides that any person who: operates a human milk bank that is not accredited and registered pursuant to the bill; has used fraud or misrepresentation in obtaining accreditation or registration or in the subsequent operation of a human milk bank; or violates any other provision of the bill is subject to a penalty of not less than \$100 or more than \$1,000 for the first offense and not less than \$500 or more than \$5,000 for the second or any subsequent offense. The bill gives the department jurisdiction to enforce and collect any penalty imposed in a summary proceeding in accordance with the "Penalty Enforcement Law of 1999." The bill provides for penalties to be recovered by the commissioner and paid into the State treasury.

The bill requires the commissioner to adopt rules and regulations in accordance with the "Administrative Procedure Act" as are necessary to effectuate the purposes of the bill.

The bill takes effect on the 180th day after the date of enactment but permits the commissioner to take anticipatory administrative actions in advance of the effective date as are necessary to implement the bill.

#### FISCAL IMPACT:

The Office of Legislative Services (OLS) finds that the bill may lead to additional State expenditures associated with accepting and processing applications for registration and conducting inspections of human milk banks. New State revenues from registration fees and penalties may offset these expenditures. However, the magnitude of these expenditures and revenues cannot be determined due to uncertainties regarding the Department of Health's implementation of



the bill and the number of milk banks that will be subject to the bill's provisions.

According to the Human Milk Banking Association of North America, there are no human milk banks that are currently located in or under development in New Jersey as of October 2016. However, human milk banks located in other states that distribute human milk in New Jersey are subject to the bill's requirements. The OLS does not know how many out-of-State human milk banks are currently operating in this State, and cannot determine how many of these may seek accreditation and registration under the bill.

The bill provides the department with discretion regarding the registration fees to be charged and the frequency of inspections. The bill specifies that annual registration fees are to be established by the department to offset its administrative costs. In the short term, uncertainty about the number of applicants could make it difficult to calibrate the fee amounts and administrative spending, but over time the OLS expects the registration program will be financially self-sustaining.

# LEGISLATIVE FISCAL ESTIMATE

[Corrected Copy]

**SENATE, No. 974**

## **STATE OF NEW JERSEY 217th LEGISLATURE**

DATED: NOVEMBER 7, 2016

### **SUMMARY**

- Synopsis:** Provides for registration and accreditation of human milk banks.
- Type of Impact:** Recurring State expenditure increase, offset by recurring State revenue increase.
- Agencies Affected:** Department of Health.

#### **Office of Legislative Services Estimate**

<b>Fiscal Impact</b>	<b><u>Annual</u></b>
<b>State Cost</b>	Indeterminate increase – See comments below
<b>State Revenue</b>	Indeterminate increase – See comments below
<b>Net Impact</b>	\$0

- The Office of Legislative Services (OLS) finds that the bill may lead to additional recurring State expenditures associated with processing applications for registration of human milk banks and conducting inspections. These costs would be offset by additional recurring State revenues from registration-related fees and penalties.
- As Of October 2016. there are no human milk banks with physical locations in or under development in New Jersey. There are several human milk banks located in other states, but the OLS does not know how many are currently distributing human milk in this State and which would therefore be required to obtain accreditation and register with the Department of Health (DOH).

### **BILL DESCRIPTION**

The Corrected Copy of Senate Bill No. 974 of 2016 would require human milk banks to be accredited by an accreditation agency for human milk banks and register with the DOH. As defined in the bill, "human milk bank" means an organized service that provides for the selection of a donor of human breast milk, the collection, processing, storage, and marketing of donated

human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed, the parent's child.

Specifically, the bill requires that a person (a person, partnership, association, agency, organization, or other similar type entity) be an accredited member of the Human Milk Bank Association of North America, and registered with the DOH, in order to operate a human milk bank in the State. A person desiring to operate a human milk bank would apply for registration in a form and in a manner prescribed by the DOH, and pay an annual registration fee established by the DOH in order to offset its administrative costs under the bill. Every five years the DOH would conduct a review to determine whether the Human Milk Bank Association of North America continues to be the most appropriate accreditation authority, and potentially change the accreditation authority.

The bill also requires the DOH to conduct on-site inspections of human milk banks at least once every five years. If an inspection finds that a human milk bank is not in compliance with requirements and guidelines of the accreditation agency, the department would notify the agency that it does not believe the bank qualifies for accreditation.

The bill gives the commissioner the authority to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the bill; or a milk bank has opened or is operating without complying with the provisions of the bill. The commissioner could also request other relief, and in any action, the court would proceed in a summary manner. Any person aggrieved by a final decision of the commissioner would be entitled to seek judicial review.

Finally, the bill stipulates that any person who: operates a human milk bank that is not accredited and registered pursuant to the bill; or who has used fraud or misrepresentation in obtaining accreditation or registration or in the subsequent operation of a human milk bank; or who violates any other provision of the bill would be subject to a penalty of not less than \$100 or more than \$1,000 for the first offense and not less than \$500 or more than \$5,000 for the second or any subsequent offense. The DOH would enforce and collect any penalty imposed in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). The penalty would be recovered by the commissioner and paid into the State treasury.

## **FISCAL ANALYSIS**

### ***EXECUTIVE BRANCH***

None received.

### ***OFFICE OF LEGISLATIVE SERVICES***

The OLS believes that the bill may lead to additional State expenditures associated with accepting and processing applications for registration, as well as conducting on-site inspections of human milk banks. New State revenues from registration fees and penalties may offset these expenditures. However, the magnitude of such expenditures and revenues cannot be determined due to uncertainties regarding the DOH's implementation of the bill and the number of milk banks that will be subject to the bill's provisions.

According to the Human Milk Banking Association of North America, there are no human milk banks with physical locations in or under development in New Jersey as of October 2016. However, human milk banks located in other states that distribute human milk in New Jersey would be subject to the bill's requirements. The OLS does not know how many out-of-State milk banks are currently operating in this State, and thus cannot determine how many of these may seek accreditation and registration under the bill.

The bill provides the DOH with some discretion regarding the registration fees to be charged and the frequency of inspections. The bill specifies that annual registration fees are to be established by the department to offset its administrative costs under the bill. In the short term, uncertainty about the number of applicants could make it difficult to appropriately calibrate the fee amounts and administrative spending, but over time the OLS expects that the registration program will be financially self-sustaining.

*Section: Human Services*

*Analyst: David Drescher  
Senior Fiscal Analyst*

*Approved: Frank W. Haines III  
Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

**STATEMENT TO**  
**SENATE, No. 974**

with Senate Floor Amendments  
(Proposed by Senator WEINBERG)

ADOPTED: JANUARY 23, 2017

These floor amendments would require human milk banks to be both accredited by, and registered with, the New Jersey State Department of Health (DOH).

As introduced, the bill would have required a human milk bank to register with the DOH, but it would have given accreditation authority to the Human Milk Bank Association of North America. The bill, as introduced, also would have required the DOH to conduct a regular review, on a five-year basis, to determine whether the Human Milk Bank Association of North America continued to be the most appropriate accreditation authority, and it would have further authorized the DOH, following such review, to change the agency responsible for accreditation. Finally, the bill, as introduced, would have required the DOH to notify the Human Milk Bank Association of North America, or other accreditation agency selected by the DOH, as applicable, whenever an on-site DOH inspection indicates that the human milk bank no longer qualifies for accreditation.

The amended bill would simplify the bill's accreditation provisions by requiring the DOH to establish and apply accreditation standards, and by authorizing the DOH to revoke accreditation if an on-site inspection reveals that the human milk bank is not in compliance with the DOH's accreditation requirements and guidelines.

The amendments also include minor technical corrections.

# LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

## SENATE, No. 974

### STATE OF NEW JERSEY 217th LEGISLATURE

DATED: FEBRUARY 16, 2017

#### SUMMARY

- Synopsis:** Provides for registration and accreditation of human milk banks.
- Type of Impact:** Recurring State expenditure increase, offset by recurring State revenue increase.
- Agencies Affected:** Department of Health.

#### Office of Legislative Services Estimate

<b>Fiscal Impact</b>	<b><u>Annual</u></b>
<b>State Cost</b>	Indeterminate increase – See comments below
<b>State Revenue</b>	Indeterminate increase – See comments below
<b>Net Impact</b>	\$0

- The Office of Legislative Services (OLS) finds that the bill may lead to additional recurring State expenditures associated with processing applications for registration of human milk banks and conducting inspections. These costs would be offset by additional recurring State revenues from registration-related fees and penalties.
- As of February 2017, there are no human milk banks with physical locations in or under development in New Jersey. Several human milk banks are located in other states, but the OLS does not know how many are currently distributing human milk in this State and which would therefore be required to obtain accreditation and register with the Department of Health (DOH).

#### BILL DESCRIPTION

Senate Bill No. 974 (1R) of 2016 would require human milk banks to be accredited by an accreditation agency for human milk banks and register with the DOH. As defined in the bill, "human milk bank" means an organized service that provides for the selection of a donor of human breast milk, the collection, processing, storage, and marketing of donated human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight

babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed, the parent's child.

Specifically, the bill requires that a person (a person, partnership, association, agency, organization, or other similar type entity) be accredited by, and registered with, the DOH. A person desiring to operate a human milk bank must adhere to guidelines established by the DOH; adhere to the best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings as required by the DOH; undergo a yearly assessment by the DOH; comply with other provisions required by the DOH; register with the department in a form and manner prescribed by the department; and pay an annual registration fee.

The bill also requires the DOH to conduct on-site inspections of human milk banks at least once every five years. If an inspection finds that a human milk bank is not in compliance with the department's requirements and guidelines, the department would revoke the agency's accreditation.

The bill gives the commissioner the authority to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the bill; or a milk bank has opened or is operating without complying with the provisions of the bill. The commissioner could also request other relief, and in any action, the court would proceed in a summary manner. Any person aggrieved by a final decision of the commissioner would be entitled to seek judicial review.

Finally, the bill stipulates that any person who: operates a human milk bank that is not accredited and registered pursuant to the bill; or who has used fraud or misrepresentation in obtaining accreditation or registration or in the subsequent operation of a human milk bank; or who violates any other provision of the bill would be subject to a penalty of not less than \$100 or more than \$1,000 for the first offense and not less than \$500 or more than \$5,000 for the second or any subsequent offense. The DOH would enforce and collect any penalty imposed in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). The penalty would be recovered by the commissioner and paid into the State treasury.

## **FISCAL ANALYSIS**

### ***EXECUTIVE BRANCH***

None received.

### ***OFFICE OF LEGISLATIVE SERVICES***

The OLS believes that the bill may lead to additional State expenditures associated with accepting and processing applications for registration and accreditation, as well as conducting on-site inspections of human milk banks. New State revenues from registration, accreditation, and inspection fees and penalties may offset these expenditures. The magnitude of such expenditures and revenues cannot be determined due to uncertainties regarding the DOH's implementation of the bill and the number of milk banks that will be subject to the bill's provisions. The bill requires an annual registration fee established by the department in order to offset its administrative costs in executing the bill, so the bill is designed to be cost-neutral. In the short term, uncertainty about the number of applicants could make it difficult to appropriately

calibrate the fee amounts and administrative spending, but over time the OLS expects that the registration program will be financially self-sustaining.

According to the Human Milk Banking Association of North America, there are no human milk banks with physical locations in or under development in New Jersey as of February 2017. However, human milk banks located in other states that distribute human milk in New Jersey would be subject to the bill's requirements. The OLS does not know how many out-of-State milk banks may seek accreditation and registration under the bill.

*Section: Human Services*

*Analyst: David Drescher  
Senior Fiscal Analyst*

*Approved: Frank W. Haines III  
Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).



# ASSEMBLY REGULATED PROFESSIONS COMMITTEE

## STATEMENT TO

[First Reprint]

**SENATE, No. 974**

# **STATE OF NEW JERSEY**

DATED: NOVEMBER 30, 2017

The Assembly Regulated Professions Committee reports favorably Senate Bill No. 974 (1R).

This bill provides for the registration and accreditation of human milk banks. As defined by the bill, a “human milk bank” is an organized service that provides for the selection of a donor of human breast milk, the collection, processing, storage, and marketing of human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed the parent's child.

The bill specifically prohibits a person from operating a human milk bank that is located in this State or from distributing donated human milk in this State unless the human milk bank is accredited by, and registered with, the Department of Health.

Under the bill, a person desiring to operate a human milk bank must:

- adhere to the guidelines for the establishment and operation of a donor human milk bank as required by the department;
- adhere to the best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings as required by the department;
- undergo a yearly assessment by the department, to provide evidence of adherence to the most recent edition of guidelines for the establishment and operation of a human milk bank;
- comply with any other provisions required by the department;
- register with the department in a form and manner prescribed by the department; and
- pay an annual registration fee established by the department to offset the department's administrative costs.

The bill requires the department to conduct an on-site facility inspection of a human milk bank at least once every five years. The inspection is to include an inspection of documents, records, files, and other data maintained by a human milk bank. If the department finds that a registered human milk bank is not in compliance with the

department's requirements and guidelines, the department is to revoke the human milk bank's accreditation.

The bill authorizes the Commissioner of Health to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the bill; or a milk bank has opened or is operating without complying with the provisions of the bill. The bill permits the commissioner to request other relief as is deemed necessary, and provides that in any such action, the court may proceed in a summary manner. Any person aggrieved by a final decision of the commissioner is entitled to seek judicial review in the Appellate Division of the Superior Court.

The bill provides that any person who: operates a human milk bank that is not accredited and registered pursuant to the bill; has used fraud or misrepresentation in obtaining accreditation or registration or in the subsequent operation of a human milk bank; or violates any other provision of the bill is subject to a penalty of not less than \$100 or more than \$1,000 for the first offense and not less than \$500 or more than \$5,000 for the second or any subsequent offense. The bill gives the department jurisdiction to enforce and collect any penalty imposed in a summary proceeding in accordance with the "Penalty Enforcement Law of 1999." The bill provides for penalties to be recovered by the commissioner and paid into the State treasury.

# ASSEMBLY, No. 1442

## STATE OF NEW JERSEY 217th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2016 SESSION

**Sponsored by:**

**Assemblywoman PAMELA R. LAMPITT**

**District 6 (Burlington and Camden)**

**Assemblywoman GABRIELA M. MOSQUERA**

**District 4 (Camden and Gloucester)**

**Assemblywoman VALERIE VAINIERI HUTTLE**

**District 37 (Bergen)**

**Assemblywoman MILA M. JASEY**

**District 27 (Essex and Morris)**

**Assemblyman THOMAS P. GIBLIN**

**District 34 (Essex and Passaic)**

**Co-Sponsored by:**

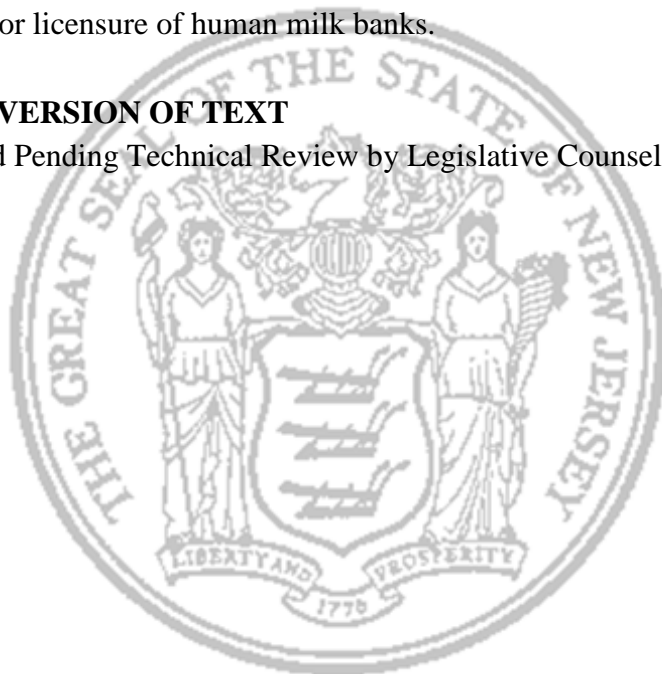
**Assemblywoman Tucker**

**SYNOPSIS**

Provides for licensure of human milk banks.

**CURRENT VERSION OF TEXT**

Introduced Pending Technical Review by Legislative Counsel.



**(Sponsorship Updated As Of: 6/23/2017)**

1 AN ACT concerning human milk banks and supplementing Title 26  
2 of the Revised Statutes.

3

4 **BE IT ENACTED** by the Senate and General Assembly of the State  
5 of New Jersey:

6

7 1. For the purposes of this act:

8 "Collection" means the obtaining of donated human breast milk.

9 "Commissioner" means the Commissioner of Health.

10 "Department" means the Department of Health.

11 "Distribution" means the removal of donated human breast milk  
12 from a human milk bank to any other location for processing or  
13 storage or for the purpose of providing breast milk to a hospital or  
14 selling breast milk to a parent.

15 "Human milk bank" means an organized service that provides for  
16 the selection of a donor of human breast milk, the collection,  
17 processing, storage, and marketing of donated human breast milk,  
18 and the distribution of donated human breast milk to a hospital for  
19 use by low birth weight babies or new mothers with delayed  
20 lactation, or directly to a parent, with a physician's prescription  
21 order, who is unable to nurse, or is in need of additional breast milk  
22 to feed, the parent's child.

23 "Licensee" means a person holding a license under the provisions  
24 of this act.

25 "Marketing" means the use of suitable media to advertise the  
26 availability of, promote the appropriate use of, and provide  
27 information on how to safely procure, donated human breast milk.

28 "Person" means a person, partnership, association, agency,  
29 organization, or other similar entity.

30 "Processing" means the technical stages required to prepare and  
31 identify donated human breast milk as to its suitability.

32 "Storage" means the holding of donated human breast milk in  
33 connection with collection or processing prior to its distribution.

34

35 2. a. A person shall not operate a human milk bank in this  
36 State unless licensed by the department pursuant to this act. A copy  
37 of the license shall be conspicuously displayed by the licensee at  
38 the premises occupied as a milk bank.

39 b. Any person desiring to operate a human milk bank shall  
40 apply to the department for a license on a form and in a manner  
41 prescribed by the commissioner. If a human milk bank meets the  
42 requirements of this act, the department shall issue a license to the  
43 milk bank. The license to operate a human milk bank shall be valid  
44 for one year from the date of issuance.

45 c. An application for renewal of the license shall be made no  
46 later than the 60th day preceding the anniversary date of licensure  
47 on a form and in a manner prescribed by the commissioner.

1 d. Each application for and renewal of a license to operate a  
2 human milk bank shall be accompanied by a fee established by the  
3 commissioner. The commissioner may periodically increase the  
4 application and renewal of application fee to reflect increased State  
5 costs in the licensure of human milk banks.

6  
7 3. a. The department shall have responsibility and authority to  
8 license and inspect human milk banks. The commissioner shall  
9 promulgate rules and regulations for the operation and maintenance  
10 of human milk banks. The regulations shall include, but not be  
11 limited to, provisions for:

12 (1) the qualifications of personnel employed in a human milk  
13 bank;

14 (2) procedures for the screening and selection of prospective  
15 donors;

16 (3) standards for the collection, processing, storage, marketing,  
17 and distribution of donated human breast milk; and

18 (4) the maintenance and confidentiality of records and  
19 furnishing of required information.

20 b. The commissioner shall also promulgate rules and  
21 regulations for license application, issuance, renewal, expiration,  
22 denial, suspension, and revocation.

23 c. At a minimum, the rules and regulations adopted pursuant to  
24 this section shall require human milk banks to be operated in  
25 accordance with protocols that have been established by the Human  
26 Milk Banking Association of North America. In addition, in  
27 promulgating rules and regulations pursuant to this section, the  
28 commissioner shall give consideration to applicable regulations or  
29 recommendations that have been adopted by other federal or  
30 national agencies or organizations.

31 d. The department shall conduct an on-site facility inspection  
32 of human milk banks and shall inspect documents, records, files, or  
33 other data maintained by a human milk bank during normal  
34 operating hours and without prior notice.

35  
36 4. The department may deny, suspend, revoke, or refuse to  
37 renew a license to operate a human milk bank for good cause,  
38 including, but not limited to:

39 a. failure of a human milk bank to comply with the provisions  
40 of this act , or the rules and regulations adopted pursuant thereto;

41 b. violation of the terms and conditions of a license by a human  
42 milk bank;

43 c. use of fraud or misrepresentation by a milk bank in  
44 obtaining a license or in the subsequent operation of the human  
45 milk bank;

46 d. refusal by a milk bank to furnish the department with  
47 required files, reports, or records; and

1 e. refusal by a human milk bank to permit an inspection by an  
2 authorized representative of the department during normal operating  
3 hours.

4  
5 5. The department, before denying, suspending, revoking, or  
6 refusing to renew a license to operate a human milk bank, shall give  
7 notice to the applicant or licensee personally, or by certified or  
8 registered mail to the last known address of the applicant or  
9 licensee with return receipt requested. The notice shall afford the  
10 applicant or licensee with an opportunity to be heard. The hearing  
11 shall take place within 60 days from the issuance or mailing of the  
12 notice and shall be conducted in accordance with the  
13 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et  
14 seq.).

15  
16 6. a. The commissioner is authorized to institute a civil action  
17 in a court of competent jurisdiction for injunctive relief to enjoin  
18 the operation of a human milk bank whenever the commissioner  
19 determines that:

20 (1) a condition exists or has occurred at the human milk bank  
21 that is dangerous to the public health;

22 (2) the human milk bank has repeatedly violated the provisions  
23 of this act; or

24 (3) a human milk bank has opened or is operating without a  
25 license or without complying with the provisions of this act.

26 b. The commissioner may, in addition, request such other relief  
27 as is deemed necessary. In any such action the court may proceed  
28 in a summary manner.

29 c. Any person aggrieved by a final decision of the  
30 commissioner shall be entitled to seek judicial review in the  
31 Appellate Division of the Superior Court. All petitions for review  
32 shall be filed in accordance with the Rules of the Court.

33  
34 7. a. Any person who operates a human milk bank that does  
35 not have a license, or who has used fraud or misrepresentation in  
36 obtaining a license or in the subsequent operation of a human milk  
37 bank, or who offers, advertises, or provides any service not  
38 authorized by a valid license, or who violates any other provision of  
39 this act shall be subject to a penalty of not less than \$100 or more  
40 than \$1,000 for the first offense and not less than \$500 or more than  
41 \$5,000 for the second or any subsequent offense.

42 b. The department shall have the jurisdiction to enforce and  
43 collect any penalty imposed because of a violation of this act in a  
44 summary proceeding in accordance with the "Penalty Enforcement  
45 Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). Process shall  
46 be in the nature of a summons or warrant and shall issue only at the  
47 suit of the commissioner as plaintiff.

1 c. A penalty recovered pursuant to the provisions of this  
2 section shall be recovered by the commissioner and paid into the  
3 State treasury.

4  
5 8. The commissioner, pursuant to the "Administrative  
6 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt  
7 rules and regulations necessary to effectuate the purposes of this  
8 act.

9  
10 9. This act shall take effect on the 180th day after the date of  
11 enactment but the commissioner may take such anticipatory  
12 administrative action in advance thereof as shall be necessary for  
13 the implementation of this act.

14  
15  
16 STATEMENT

17  
18 This bill would provide for the licensure of human milk banks. As  
19 defined in the bill, "human milk bank" means an organized service for  
20 the selection of a donor of human breast milk, the collection,  
21 processing, storage, and marketing of donated human breast milk, and  
22 the distribution of donated human breast milk to a hospital for use by  
23 low birth weight babies or new mothers with delayed lactation, or  
24 directly to a parent, with a physician's prescription order, who is  
25 unable to nurse, or is in need of additional breast milk to feed, the  
26 parent's child.

27 Specifically, the bill requires that a person (a person, partnership,  
28 association, agency, organization, or other similar type entity) be  
29 licensed by the Department of Health (DOH) in order to operate a  
30 human milk bank in the State. A copy of the license would be  
31 displayed on the premises of the milk bank.

32 Under the provisions of the bill, a person desiring to operate a  
33 human milk bank would apply for a license on a form and in a manner  
34 prescribed by the Commissioner of Health. If a human milk bank  
35 meets the requirements of this act, DOH would issue a license to the  
36 milk bank and the license would be valid for one year.

37 An application to renew a license would be made 60 days prior to  
38 the anniversary date of licensure and each application for and renewal  
39 of a license to operate a human milk bank would be accompanied by a  
40 fee established by the commissioner. The commissioner would be  
41 allowed to periodically increase the application and renewal fees to  
42 reflect increased State costs in licensing milk banks.

43 The bill also gives DOH the authority to license and inspect human  
44 milk banks, including an inspection of records, files, and other data,  
45 and requires the commissioner to promulgate rules and regulations for  
46 the operation and maintenance of human milk banks. The rules and  
47 regulations governing human milk banks would include provisions for:  
48 staff qualifications; procedures for selecting and screening potential

1 donors; standards for the collection, processing, storage, marketing,  
2 and distribution of donated breast milk; the maintenance and  
3 confidentiality of milk bank records; and license application, issuance,  
4 renewal, expiration, denial, suspension, and revocation. The bill  
5 would require the rules and regulations, at a minimum, to require  
6 human milk banks to be operated in accordance with protocols that  
7 have been established by the Human Milk Banking Association of  
8 North America. In addition, in promulgating rules and regulations, the  
9 commissioner would also be required to consider applicable  
10 regulations or recommendations that have been adopted by other  
11 federal or national agencies or organizations.

12 DOH would be allowed to deny, suspend, revoke, or refuse to  
13 renew a license to a human milk bank for good cause, and would be  
14 required to give notice to an applicant or a licensee before denying,  
15 suspending, revoking, or refusing to renew a license. The applicant or  
16 licensee would be noticed personally or by certified or registered mail  
17 to the applicant's or licensee's last known address with return receipt  
18 requested in order to afford the applicant or licensee an opportunity to  
19 be heard. The hearing would take place within 60 days from the  
20 issuance or mailing of the notice.

21 The bill gives the commissioner the authority to institute a civil  
22 action to enjoin the operation of a human milk bank whenever the  
23 commissioner determines that: a condition exists or has occurred at the  
24 human milk bank that is dangerous to the public health; a milk bank  
25 has repeatedly violated the provisions of the bill; or a milk bank has  
26 opened or is operating without a license or without complying with the  
27 provisions of the bill.

28 The commissioner could also request other relief, and in any  
29 action, the court would proceed in a summary manner. Any person  
30 aggrieved by a final decision of the commissioner would be entitled to  
31 seek judicial review.

32 Finally, the bill stipulates that any person who: operates a human  
33 milk bank that does not have a license; has used fraud or  
34 misrepresentation in obtaining a license or in the subsequent operation  
35 of a human milk bank; offers, advertises, or provides any service not  
36 authorized by a valid license; or violates any other provision of the bill  
37 would be subject to a penalty of not less than \$100 or more than  
38 \$1,000 for the first offense and not less than \$500 or more than \$5,000  
39 for the second or any subsequent offense. DOH would enforce and  
40 collect any penalty imposed in accordance with the "Penalty  
41 Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).  
42 The penalty would be recovered by the commissioner and paid into the  
43 State treasury.



# ASSEMBLY REGULATED PROFESSIONS COMMITTEE

## STATEMENT TO

### ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, No. 1442

# STATE OF NEW JERSEY

DATED: NOVEMBER 30, 2017

The Assembly Regulated Professions Committee reports favorably Assembly Committee Substitute for Assembly Bill No. 1442.

This committee substitute provides for the registration and accreditation of human milk banks. As defined by the committee substitute, a “human milk bank” is an organized service that provides for the selection of a donor of human breast milk, the collection, processing, storage, and marketing of human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed the parent's child.

The committee substitute specifically prohibits a person from operating a human milk bank that is located in this State or from distributing donated human milk in this State unless the human milk bank is accredited by, and registered with, the Department of Health.

Under the committee substitute, a person desiring to operate a human milk bank must:

- adhere to the guidelines for the establishment and operation of a donor human milk bank as required by the department;
- adhere to the best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings as required by the department;
- undergo a yearly assessment by the department, to provide evidence of adherence to the most recent edition of guidelines for the establishment and operation of a human milk bank;
- comply with any other provisions required by the department;
- register with the department in a form and manner prescribed by the department; and
- pay an annual registration fee established by the department to offset the department's administrative costs.

The committee substitute requires the department to conduct an on-site facility inspection of a human milk bank at least once every five years. The inspection is to include an inspection of documents, records, files, and other data maintained by a human milk bank. If the department finds that a registered human milk bank is not in

compliance with the department's requirements and guidelines, the department is to revoke the human milk bank's accreditation.

The committee substitute authorizes the Commissioner of Health to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the substitute; or a milk bank has opened or is operating without complying with the provisions of the committee substitute. The committee substitute permits the commissioner to request other relief as is deemed necessary, and provides that in any such action, the court may proceed in a summary manner. Any person aggrieved by a final decision of the commissioner is entitled to seek judicial review in the Appellate Division of the Superior Court.

The committee substitute provides that any person who: operates a human milk bank that is not accredited and registered pursuant to the committee substitute; has used fraud or misrepresentation in obtaining accreditation or registration or in the subsequent operation of a human milk bank; or violates any other provision of the committee substitute, is subject to a penalty of not less than \$100 or more than \$1,000 for the first offense and not less than \$500 or more than \$5,000 for the second or any subsequent offense. The committee substitute gives the department jurisdiction to enforce and collect any penalty imposed in a summary proceeding in accordance with the "Penalty Enforcement Law of 1999." The committee substitute provides for penalties to be recovered by the commissioner and paid into the State treasury.

**LEGISLATIVE FISCAL ESTIMATE**  
**ASSEMBLY COMMITTEE SUBSTITUTE FOR**  
**ASSEMBLY, No. 1442**  
**STATE OF NEW JERSEY**  
**217th LEGISLATURE**

DATED: DECEMBER 12, 2017

**SUMMARY**

**Synopsis:** Provides for registration and accreditation of human milk banks.

**Type of Impact:** Recurring State expenditure increase; offset by recurring State revenue increase.

**Agencies Affected:** Department of Health.

**Office of Legislative Services Estimate**

<b>Fiscal Impact</b>	<u><b>Annual</b></u>
<b>State Cost</b>	Indeterminate increase – See comments below
<b>State Revenue</b>	Indeterminate increase – See comments below
<b>Net Impact</b>	\$0

- The Office of Legislative Services (OLS) finds that the bill may lead to additional recurring State expenditures associated with processing applications for registration of human milk banks and conducting inspections. These costs would be offset by additional recurring State revenues from registration-related fees and penalties.
- As of December 2017, there are no human milk banks with physical locations in or under development in New Jersey. Several human milk banks are located in other states, but the OLS does not know how many are currently distributing human milk in this State and which would therefore be required to obtain accreditation and register with the Department of Health (DOH).

**BILL DESCRIPTION**

The Assembly Committee Substitute for Assembly Bill No. 1442 of 2017 would require human milk banks to be accredited by an accreditation agency for human milk banks and register with the DOH. As defined in the bill, "human milk bank" means an organized service that

provides for the selection of a donor of human breast milk, the collection, processing, storage, and marketing of donated human breast milk, and the distribution of donated human breast milk to a hospital for use by low birth weight babies or new mothers with delayed lactation, or directly to a parent, with a physician's prescription order, who is unable to nurse, or is in need of additional breast milk to feed, the parent's child.

Specifically, the bill requires that a person (a person, partnership, association, agency, organization, or other similar type entity) be accredited by, and registered with, the DOH. A person desiring to operate a human milk bank must adhere to guidelines established by the DOH; adhere to the best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings as required by the DOH; undergo a yearly assessment by the DOH; comply with other provisions required by the DOH; register with the department in a form and manner prescribed by the department; and pay an annual registration fee.

The bill also requires the DOH to conduct on-site inspections of human milk banks at least once every five years. If an inspection finds that a human milk bank is not in compliance with the department's requirements and guidelines, the department would revoke the agency's accreditation.

The bill gives the commissioner the authority to institute a civil action to enjoin the operation of a human milk bank whenever the commissioner determines that: a condition exists or has occurred at the human milk bank that is dangerous to the public health; a milk bank has repeatedly violated the provisions of the bill; or a milk bank has opened or is operating without complying with the provisions of the bill. The commissioner could also request other relief, and in any action, the court would proceed in a summary manner. Any person aggrieved by a final decision of the commissioner would be entitled to seek judicial review.

Finally, the bill stipulates that any person who: operates a human milk bank that is not accredited and registered pursuant to the bill; or who has used fraud or misrepresentation in obtaining accreditation or registration or in the subsequent operation of a human milk bank; or who violates any other provision of the bill would be subject to a penalty of not less than \$100 or more than \$1,000 for the first offense and not less than \$500 or more than \$5,000 for the second or any subsequent offense. The DOH would enforce and collect any penalty imposed in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). The penalty would be recovered by the commissioner and paid into the State treasury.

## **FISCAL ANALYSIS**

### ***EXECUTIVE BRANCH***

None received.

### ***OFFICE OF LEGISLATIVE SERVICES***

The OLS believes that the bill may lead to additional State expenditures associated with accepting and processing applications for registration and accreditation, as well as conducting on-site inspections of human milk banks. New State revenues from registration, accreditation, and inspection fees and penalties may offset these expenditures. The magnitude of such expenditures and revenues cannot be determined due to uncertainties regarding the DOH's implementation of the bill and the number of milk banks that will be subject to the bill's provisions. The bill requires an annual registration fee established by the department in order to

offset its administrative costs in executing the bill, so the bill is designed to be cost-neutral. In the short term, uncertainty about the number of applicants could make it difficult to appropriately calibrate the fee amounts and administrative spending, but over time the OLS expects that the registration program will be financially self-sustaining.

According to the Human Milk Banking Association of North America, there are no human milk banks with physical locations in or under development in New Jersey as of December 2017. However, human milk banks located in other states that distribute human milk in New Jersey would be subject to the bill's requirements. The OLS does not know how many out-of-State milk banks may seek accreditation and registration under the bill.

*Section: Human Services*

*Analyst: David Drescher  
Senior Fiscal Analyst*

*Approved: Frank W. Haines III  
Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).