

SENATE APPROPRIATIONS COMMITTEE FISCAL NOTE

BILL NO. House Bill 1001

PRINTER'S NO. 2884

AMOUNT

No Fiscal Impact

FUND

General Fund

DATE INTRODUCED

March 27, 2019

PRIME SPONSOR

Representative Oberlander

DESCRIPTION AND PURPOSE OF BILL

House Bill 1001 establishes the Keystone Mothers' Milk Bank Act (act) to license and regulate milk banks in the Commonwealth.

House Bill 1001 defines "milk bank" as an entity that collects donor milk from medically screened human donors and distributes the donor milk to medically fragile children other than the donor's own child based on a health care provider's order or prescription.

Licensure:

The bill requires the Department of Health (department) to license any entity currently operating or seeking to operate a milk bank in the Commonwealth. In addition to meeting the requirements of the act, the entity must either:

- Be a member in good standing of a nationally recognized professional organization for the operation of milk banks; or
- Be in compliance with the requirements of the act.

The bill stipulates that the department must inspect the facility prior to the issuance of a license. A license shall expire two years after the date of issuance. An entity is required to pay an initial license fee of \$1,000 and \$250 for a license renewal.

The bill provides if the application is denied the department shall provide written explanation for any denial. The bill also allows the department to revoke or suspend a license for failure to comply with the provisions of the act or regulations promulgated by the department.

The bill permits a milk bank that was in operation prior to the act to continue to operate pending a decision on its application if the application is made within 120 days of the later of the following:

- The effective date of the licensure requirements; or
- The date that an application for a license is first made available to prospective licensees under the act.

SENATE APPROPRIATIONS COMMITTEE

FISCAL NOTE

Operation of Milk Bank:

House Bill 1001 requires licensees to develop and implement policies and procedures necessary to implement the act and to have a managing director, medical director and medical advisory committee. A milk bank must have a board of directors or similar body that is ultimately responsible to ensure compliance and provide oversight over the director, medical director and medical advisory committee.

The bill sets forth the following standards for documents and record retention policies:

- Requires individual donor files to contain the donor's consent to participate and any laboratory test results;
- Prohibits disclosure of any direct or indirect identifying information without the donor's written consent; and
- Provides for provisions to trace donated milk from donor to distribution, including identification numbers, dates, multi-source pooling, bacteriological testing information, storage requirements and tracking and shipping information.

The bill requires milk banks to notify the department within 10 days of establishing a relationship with a dispensary or satellite milk depot and for each licensee to publicly display the license.

Donor Qualifications:

The bill provides that potential donors must do the following:

- Be medically screened initially and periodically reassessed;
- Provide consent for the milk bank to contact the donor's and the donor's biological baby health care providers to obtain approval for medical screening and blood testing and verify that the baby is achieving adequate growth;
- Be excluded from donation if found to have a blood borne pathogen infection or infectious disease; and
- Be temporarily precluded from donation if using certain medications, have a systemic chronic disease, have a history of possible exposure to environmental contaminants, or lack ability to comprehend sanitary collection and storage requirements.

Donor Milk Processing:

House Bill 1001 requires donor milk to be processed utilizing an approved pasteurization or processing method, as well as to perform post-pasteurization bacteriologic cultures. It provides specific requirements for labeling and identifying containers of unprocessed milk and frozen, unprocessed milk and processed milk. House Bill 1001 also provides for storage requirements, including proper refrigeration and freezing, the packing of processed milk, transportation and shipping.

SENATE APPROPRIATIONS COMMITTEE

FISCAL NOTE

Duties of the Department:

House Bill 1001 requires the department to license and regulate the operation of milk banks in the Commonwealth. The department must also review professional association guidelines and adopt standards and requirements for licensure to ensure and maintain the safe operation and certification of licensees. Additionally, the department must inspect a milk bank's physical facilities and the physical facilities of a dispensary or satellite milk depot.

The bill provides that the department can suspend or revoke a license under the act, so long as the department provides written notification to the licensee specifying the reasons for revocation or suspension and designates a time and place for a hearing to be held within 30 days of the notification.

The bill stipulates that the department must issue a report in odd numbered years with respect to milk banks and report the following:

- Number of licensed milk banks in Pennsylvania;
- Address of each milk bank;
- Summary of the amount of milk donated, processed and distributed by each milk bank; and
- Any other information deemed relevant by the department.

Violations:

House Bill 1001 provides for the following prohibitions, with each constituting a misdemeanor of the third degree:

- Operation of a milk bank in the Commonwealth by a person not licensed under the act;
- Direct or indirect sale of human milk for profit or a service fee by a milk bank not licensed under the act; and
- Remuneration of value provided to a milk donor by an entity, except as permitted by the act.

Exceptions:

The bill permits the following exceptions:

- A milk bank located in the Commonwealth and subject to the hospital licensure process is exempt from licensure under the act;
- If a milk bank, licensed under the act, lacks access to donor milk or a specific type of milk ordered or prescribed to a Pennsylvania resident, that donor milk may be procured from an out-of-state milk bank approved by a professional organization or the department; and
- An exemption for a milk bank to grant remuneration to donors, approved by the department.

Creation of an application for licensure of milk banks and regulations promulgated under the act shall take effect immediately. The remainder of the act shall take effect in 120 days.

SENATE APPROPRIATIONS COMMITTEE

FISCAL NOTE

FISCAL IMPACT:

House Bill 1001 will have no fiscal impact to the Commonwealth. There is currently only one milk bank operating in Pennsylvania (not exempt) that would be subject to licensing due to enactment of this legislation. Therefore, licensure and oversight costs should be minimal and covered within existing funding provided to the Department of Health. Additionally, revenue generated through licensing activities is anticipated to be \$1,000 in the initial year following enactment.

In addition, the bill requires the Department of Health to promulgate regulations and create an application for licensure, which can be accomplished within existing staffing levels and funding provided to the department.