



HOUSE COMMITTEE ON APPROPRIATIONS

FISCAL NOTE

HOUSE BILL NO. 1001

PRINTERS NO. 1126

PRIME SPONSOR: Oberlander

COST / (SAVINGS)

FUND	FY 2018/19	FY 2019/20
General Fund	\$0	See Fiscal Impact

SUMMARY: House Bill 1001, Printer's Number 1126, establishes the freestanding Keystone Mothers' Milk Bank Act. This legislation is effective in 120 days except the regulations promulgated under this Act are effective immediately.

ANALYSIS: HB 1001 creates a freestanding act to establish rigorous standards for the licensure and regulation of milk banks in Pennsylvania. A "milk bank" is an entity which collects and stores donated human milk for distribution in accordance with an order or prescription from a health care provider.

Licensure/Inspection:

This legislation requires the Department of Health (DOH) to establish a licensure and inspection process for a facility which seeks to operate a milk bank. The entity must:

- Be a member in good standing with the Human Milk Bank Association of North America (HMBANA);
- Be a member of another nationally recognized accrediting organization for the operation of milk banks; or
- Be in compliance with the requirements of this Act.

An entity shall pay a \$1,000 fee for an initial license and \$250 for each license renewal. The facility must be inspected prior to issuance of a license. The license to operate is good for two years and may be denied, suspended or revoked for failure to comply with the provisions of this Act or regulations promulgated by DOH.

Operation of Milk Banks:

DOH is directed to regulate the operation of milk banks, including review of the American Academy of Pediatrics guidelines and HMBANA policies in development of those regulations.

The bill prescribes duties to be performed by the director of the milk bank:

- Develop and implement policies and procedures
- Appoint a medical director who is a licensed physician with 4 years of experience in a relevant field
- Appoint a medical advisory committee for the milk bank

HB 1001 also creates minimum standards for documents and record retention policies. These policies include how donor medical information is stored; the tracing of donated milk from donation to delivery to the patient; the pooling of multi-source milk products; and bacterial testing information and dates.

Donor Qualifications:

The bill requires donors be medically screened initially and periodically reassessed to determine conditions and behaviors that may impact the nutritional value of the donor's milk. The health screening process may also extend from the donor to the donor's child and include their relevant health records from health care practitioners. Donors shall be excluded from donation for a documented infection by a bloodborne pathogen or for other acute or chronic infectious diseases.

Donors may be temporarily precluded from donating milk if there are contraindications with respect to medication, tobacco or other substances identified in the milk or other environmental toxins found in the milk. Donors can also be temporarily suspended if a donor's infant is in need of additional nutrition.

Donor Milk Processing:

Donated milk must be processed, stored and distributed in a manner which allows for the tracking of the milk source and end product. The pasteurization process to be used shall be approved by HMBANA in order to ensure all pathogens are removed from the donor milk.

Storage of the milk from donation to distribution is to be done in a manner which is consistent with the FDA standards for other food products, and in a container that is approved for heating and freezing of food products.

Duties of the Department:

DOH shall license and regulate the operation of milk banks in Pennsylvania including adopting standards and requirements for licensure which will maintain the safe operation and certification of licensees. DOH is required to inspect the physical facilities of a dispensary and satellite milk depot.

DOH shall issue a report in odd numbered years with respect to the milk banks. The report shall contain:

- The number of licensed milk banks in PA
- Address of each milk bank
- Summary of the amount of milk donated, processed and distributed by each milk bank
- Any other information deemed relevant by DOH

Exemptions:

A milk bank in PA which is operated by a hospital and subject to the hospital licensure process shall be exempt from licensure under this Act. DOH may also allow an exemption for a milk bank to grant remuneration to donors.

FISCAL IMPACT: There is currently one known milk bank operating in Pennsylvania that would be subject to licensing due to enactment of this legislation, therefore costs should be minimal and covered within existing funding.

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House Appropriations Committee (R)

DATE: June 3, 2019

Estimates are calculated using the best information available. Actual costs and revenue impact incurred may vary from estimates.