

# SENATE BUDGET AND APPROPRIATIONS COMMITTEE

## STATEMENT TO

[First Reprint]

**SENATE, No. 1209**

# **STATE OF NEW JERSEY**

DATED: JUNE 8, 2015

The Senate Budget and Appropriations Committee reports favorably Senate Bill No. 1209 (1R).

This bill provides for the licensure of human milk banks. As defined in the bill, "human milk bank" means an organized service 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 licensed by the Department of Health (DOH) in order to operate a human milk bank in the State. A copy of the license will be required to be displayed on the premises of the milk bank.

Under the bill, a person desiring to operate a human milk bank must apply for a license on a form and in a manner prescribed by the Commissioner of Health. If a human milk bank meets the requirements of this act, DOH will issue a license to the milk bank that is valid for one year. An application to renew an annual license is required to be made 60 days prior to the anniversary date of licensure and each application for and renewal of a license to operate a human milk bank will be accompanied by a fee established by the commissioner. The commissioner is allowed to periodically increase the application and renewal fees to reflect increased State costs in licensing milk banks.

The bill also gives DOH the authority to license and inspect human milk banks, including an inspection of records, files, and other data, and requires the commissioner to promulgate rules and regulations for the operation and maintenance of human milk banks. The rules and regulations governing human milk banks will include provisions for: staff qualifications; procedures for selecting and screening potential donors; standards for the collection, processing, storage, marketing, and distribution of donated breast milk; the maintenance and

confidentiality of milk bank records; and license application, issuance, renewal, expiration, denial, suspension, and revocation. The bill requires that the rules and regulations, at a minimum, require human milk banks to be operated in accordance with protocols that have been established by the Human Milk Banking Association of North America. In addition, in promulgating rules and regulations, the commissioner will be required to consider applicable regulations or recommendations that have been adopted by other federal or national agencies or organizations.

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

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 a license or without complying with the provisions of the bill.

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

Finally, the bill stipulates that any person who: operates a human milk bank that does not have a license; has used fraud or misrepresentation in obtaining a license or in the subsequent operation of a human milk bank; offers, advertises, or provides any service not authorized by a valid license; or violates any other provision of the bill may 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. DOH will 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 will be recovered by the commissioner and paid into the State Treasury.

**FISCAL IMPACT:**

The Office of Legislative Services (OLS) notes that the bill may lead to additional State expenditures associated with processing licensure applications and conducting inspections, potentially offset by additional State revenues from licensure-related fees and penalties. However, the magnitude of such expenditures and revenues cannot be

determined due to uncertainties regarding the manner in which the Department of Health (DOH) will choose to implement the bill and the number of milk banks that would seek licensure.

There are currently 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 operating in this State, and cannot determine how many of these may seek licensure under the bill. There appear to be several informal internet-based milk sharing networks operating in New Jersey, but it is not certain if any of these networks would require licensure under the bill.