

PROVISIONAL REGISTRATION AND ACCREDITATION REQUIREMENTS FOR HUMAN MILK BANKS (PRA-HMB)

New Jersey Department of Health Biobanking Compliance Program

The New Jersey Department of Health is providing notice of the requirements and procedures for obtaining Provisional Registration and Accreditation (PRA) status for your human milk bank (HMB) facility that is either located in the State of New Jersey or distributes donated human milk in the State of New Jersey.

APPLICABILITY

Pursuant to N.J.S.A. 26:2A-17, a "human milk bank" is defined as:

"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."

"Distribution" is defined as:

"The removal of donated human breast milk from a human milk bank to any other location for processing or storage or for the purpose of providing breast milk to a hospital or selling breast milk to a parent."

MANDATORY REGISTRATION AND ACCREDITATION

Pursuant to N.J.S.A. 26:2A-18:

"A person shall not operate a human milk bank that is located in this State or distributes donated human milk in this State unless the human milk bank is accredited by, and registered with, the department pursuant to this act."

If your organization meets the definition of a human milk bank and is either located in New Jersey, distributes donated human milk in New Jersey, or performs any human milk bank services in New Jersey, registration and accreditation with the Department is legally required. The following requirements apply.

CRITICAL COMPLIANCE DEADLINES

- **Notice of Intention Deadline: June 17, 2026**
- **Full Application Deadline: July 17, 2026**

ELIGIBILITY CRITERIA

To qualify for provisional registration and accreditation status, your facility must meet the following requirements:

- Full operational status as of May 18, 2026
- Good standing with applicable accrediting body (HMBANA) and/or FDA
- Full compliance with all applicable Federal standards and approved plans of correction
- If operating in jurisdictions outside New Jersey, compliance with all applicable standards and plans of correction in those jurisdictions

REQUIRED ACTION 1: SUBMISSION OF NOTICE OF INTENTION

Due: June 17, 2026

Submit notice to the Biobanking Compliance Program at clis.biobanking@doh.nj.gov containing:

- Written notice of intention to apply for registration and accreditation as an RA-HMB, certifying therein compliance with all eligibility criteria stated above
- Include the following information:
 - Name of HMB
 - Name of Applicant (HMB Owner or Operator)
 - Mailing Address of HMB
 - Mailing Address of Owner or Operator
 - Physical Address of HMB
 - Telephone Number of HMB
 - Telephone Number of HMB Owner or Operator
 - HMB Email Address

- Owner or Operator Email Address

Upon receipt of your notice, the Biobanking Compliance Program will issue a certificate of provisional registration and accreditation.

REQUIRED ACTION 2: ALIS PORTAL ACCESS ESTABLISHMENT

To submit your full application, you must first establish access to the ALIS (Application and Licensure Information System) portal:

1. Create MyNJ Account (if not previously established):

- Navigate to www.nj.gov
- Select "Login to myNJ" at the top of the webpage
- Select "Sign Up"
- Complete all required fields
- Select "Create Account"

2. Request ALIS Portal Access:

- Send email to clis.biobanking@doh.nj.gov with subject line "ALIS Access Request"
- Include the following information:
 - Applicant name
 - Facility name
 - Physical address
 - Telephone number
 - Email address

3. Activate ALIS Access:

- Enter the access code provided by the Biobanking Compliance Program into your MyNJ account
 - Upon completion, ALIS portal access will be granted
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REQUIRED ACTION 3: FULL APPLICATION SUBMISSION

Due: July 17, 2026

Complete and submit the full registration and accreditation application through the ALIS portal in accordance with N.J.A.C. 8:75-2.1.

COMPLIANCE NOTICE

Please be advised that operation of a human milk bank facility without provisional registration and accreditation subjects your organization to enforcement action pursuant to N.J.S.A. 26:2A-18, 20, and 21. Your provisional status will remain effective until the Department issues a final determination on your application or until abandonment of the application pursuant to N.J.A.C. 8:75-2.1(c)3.

Additionally, your facility remains responsible for submitting reportable events to the Department pursuant to N.J.A.C. 8:75-3.6 during the pendency of your provisional status.

CONTACT INFORMATION

For questions or technical assistance:

New Jersey Department of Health
Public Health and Environmental Laboratories
Clinical Laboratory Improvement Services
Biobanking Compliance Program

Email: clis.biobanking@doh.nj.gov

Telephone: 609-718-8173