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MEMO

TO: New Jersey Acute Care Hospitals
FROM: Alan Rimmer, MD, Executive Director, Clinical Laboratory Improvement Services
SUBJECT: Paolo Ata, DHSc, Manager, Biobanking Compliance Program
Guidance Memorandum Concerning the Human Milk Bank
Registration and Accreditation Requirements for Acute Care Hospitals under N.J.A.C. 8:75
DATE: August 27, 2026

On July 31, 2026, the New Jersey Department of Health (Department), Clinical Laboratory Improvement Services, Biobanking Compliance Program issued a notification to New Jersey acute care hospitals advising of the recently promulgated Human Milk Bank (HMB) rules, N.J.A.C. 8:75, and requesting that those hospitals engaging in human milk banking apply for HMB registration and accreditation, as required by the rules. Thereafter, the Department received multiple inquiries from hospitals seeking guidance on whether their specific human milk bank services required registration and accreditation under the rules. In response, the Department is issuing this guidance document to supplement its July 31, 2026 notification.

N.J.S.A. 26:2A-17 defines a "human milk bank" 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." See also N.J.A.C. 8:75-1.2. N.J.A.C. 8:75-2.1 requires that any person seeking to operate a human milk bank and/or perform any HMB service in the State must apply for registration and accreditation with the Department.

Based upon the above definition of "human milk bank," a hospital that purchases or obtains processed human milk or products containing processed human milk for purposes of dispensing it directly to a patient in the hospital is not obtaining human breast milk from donors and is not distributing, processing, or holding human breast milk in connection with the collection or processing.

The Department is aware that several hospital NICUs in the State operate in this manner. Accordingly, when a hospital's human milk banking activity is **limited to** procuring processed human breast milk (PHM) directly from a Human Milk Bank (HMB) that is registered and accredited by the Department (RA-HMB) and storage of that PHM until it is dispensed directly to an inpatient of the hospital, whether in a neonatal intensive care unit (NICU) or otherwise, the hospital/unit is

not required to be registered and accredited as an HMB.

Additionally, a hospital that distributes information to its patients about how to safely procure donated human breast milk as a form of patient education is not engaging in marketing of human milk, as outlined in the definition. Thus, a hospital that is providing this service is not deemed to be performing human milk bank services that would require registration and accreditation with the Department.

However, any hospital unit or program that engages in any of the following activities **must become registered and accredited by the Department as a human milk bank**:

- selecting milk donors;
- obtaining raw or frozen human breast milk directly from donors by functioning as a depot or otherwise;
- processing human breast milk;
- holding donated human breast milk in connection with collection or processing prior to distribution ("storage" as defined at N.J.S.A. 26:2A-17);
- distributing PHM (whether procured from an RA-HMB or processed by the hospital itself) to anyone other than an inpatient of the hospital; or
- marketing.

Moreover, if a hospital distributes PHM to a parent who holds an order from a physician, or who is unable to nurse, or is otherwise in need of additional breast milk to feed the parent's child, and neither the parent nor the child is currently an inpatient at that hospital, then the hospital must obtain a registration and accreditation from the Department to provide the service.

The Department will continue to monitor and evaluate this new regulatory program and may make appropriate amendments through future rulemaking as necessary to protect public health and support the availability of safe PHM for infants in need in New Jersey.

Thank you for your cooperation and attention to this regulatory requirement.

Please see <https://www.nj.gov/health/phel/clinical-lab-imp-services/biobanking-compliance/> for contact information, application forms, and other useful information.