HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

BIOBANKING COMPLIANCE PROGRAM

Human Milk Bank Registration and Accreditation

Proposed New Rules: N.J.A.C. 8:75

Authorized By: Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health.

Authority: N.J.S.A. 26:2A-17 through 26:2A-22, specifically, 26:2A-22; and P.L. 2017, c. 247, § 7.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2025-042.

Submit written comments by June 20, 2025, electronically to www.nj.gov/health/legal/ecomments.shtml or by regular mail postmarked by June 20, 2025, to:

Genevieve Raganelli, Regulatory Officer

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

On January 8, 2018, the Governor approved P.L. 2017, c. 247, codified in part at N.J.S.A. 26:2A-17 through 22 (the Act), which was effective July 7, 2018. The Act establishes standards for the operation of donor human milk banks in the State. The Act 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." N.J.S.A. 26:2A-17.

The Act prohibits the performance of human milk bank (HMB) services (collection, distribution, marketing, processing, and storage of donated human milk) in the State unless the person obtains registration and accreditation from the Department of Health (Department), and adheres to Department standards for the establishment and operation of an HMB and best practices for expressing, storing, and handling human milk in hospitals, homes, and child care settings. N.J.S.A. 26:2A-18. The Act requires the Department to conduct an annual assessment to review evidence of the registrant's adherence to "the most recent edition of guidelines for the establishment and operation of a human milk bank." *Id.*

The Act requires the Department to conduct an on-site facility inspection of a registered and accredited HMB (RA-HMB) at least once every five years, which is to include inspection of documents, records, files, and other data maintained by the RA-HMB to assess its compliance with the Act and Department requirements; and to revoke the RA-HMB's registration and accreditation if the Department finds that the RA-HMB is not in compliance. N.J.S.A. 26:2A-19.

The Act authorizes the Commissioner of the Department (Commissioner) to institute a civil action to enjoin the operation of an HMB, and to request other relief as the Commissioner of the Department (Commissioner) deems necessary whenever the Commissioner determines that a condition exists or has occurred at the HMB that is dangerous to public health, the HMB has repeatedly violated the provisions of the Act, or is operating an HMB without complying with the Act. N.J.S.A. 26:2A-20. The Act provides that in any such action, the court may proceed in a summary manner and that a person aggrieved by a final decision of the Commissioner can seek judicial review in the Appellate Division of the Superior Court. *Id.*

The Act provides that a person who operates an HMB that is not registered and accredited pursuant to the Act, has used fraud or misrepresentation in obtaining registration or accreditation or in the subsequent operation of an HMB, or violates any other provision of the Act, is subject to a penalty of not less than $100.00 or more than $1,000 for a first offense, and not less than $500.00 or more than $5,000 for a second

or any subsequent offense. N.J.S.A. 26:2A-21. The Act authorizes the Department to enforce and collect any penalty imposed for a violation of the Act in a summary proceeding in accordance with the Penalty Enforcement Law of 1999, and provides that any penalty that the Commissioner recovers in such a proceeding is to be deposited into the State Treasury. *Id.*

The Act directs the Commissioner to promulgate rules to implement the Act. N.J.S.A. 26:2A-22. See also P.L. 2017, c. 247, § 7 (authorizing the Commissioner to take anticipatory administrative action to implement the Act). To implement the rulemaking obligations that the Act establishes, as described above, the Department is proposing new rules at N.J.A.C. 8:75, Human Milk Bank Registration and Accreditation.

Subchapter 1 would establish general provisions. Proposed new N.J.A.C. 8:75-1.1, Purpose and scope, would establish the purpose and scope of the chapter. Proposed new N.J.A.C. 8:75-1.2, Definitions, would establish definitions of words and terms the chapter uses. Among these is the Department's newly established Biobanking Compliance Program within Clinical Laboratory Improvement Services, located at New Jersey Public Health, Environmental, and Agricultural Laboratory, PO Box 361, Trenton, NJ 08625-0361, which will administer this and other regulatory programs. Proposed new N.J.A.C. 8:75-1.3, Federal standards and regulatory guidance documents, would identify Federal standards and guidance documents that the chapter incorporates by reference, as amended and supplemented. Proposed new N.J.A.C. 8:75-1.4, AAP guidance, would identify guidance publications and position statements that the American Academy of Pediatrics (AAP) issues, which the chapter incorporates by reference, as amended and supplemented. Proposed new N.J.A.C. 8:75-1.5, Waiver, would establish a standard and procedure by which an entity that is subject to the chapter could apply to the Department for a waiver of a provision of the chapter.

Subchapter 2, Issuance and Renewal of Registration and Accreditation; Inspection; Fees, would establish standards for issuance and renewal of registration and accreditation, inspection standards, and applicable fees. Proposed new N.J.A.C. 8:75-2.1, Application for registration and accreditation; authorized HMB services, would establish standards by which one may apply to the Department for registration and

accreditation of an HMB, and would identify authorized HMB services. Proposed new N.J.A.C. 8:75-2.2, Registration and accreditation criteria, would establish the criteria pursuant to which the Department would register and accredit an HMB. Proposed new N.J.A.C. 8:75-2.3, Registration and accreditation by deemed status, would establish the standards by which the Department would issue registration and accreditation by deemed status, which would apply to HMBs that maintain accreditation in good standing by an accrediting body. Presently, only one entity in the United States of America engages in HMB accreditation. That entity only accredits HMBs that perform HMB services as nonprofit entities. Proposed new N.J.A.C. 8:75-2.4, Inspection, would establish standards for Department inspection of applicants for registration and accreditation as HMBs and renewal of registration and accreditation of existing RA-HMBs. Proposed new N.J.A.C. 8:75-2.5, Certificate of registration and accreditation, would describe the certificate of registration and accreditation that the Department will issue upon granting an application. Proposed new N.J.A.C. 8:75-2.6, Renewal of registration and accreditation, would establish the procedure by which an RA-HMB would apply for renewal of its registration and accreditation. Proposed new N.J.A.C. 8:75-2.7, Fees, travel costs, would establish the fees the Department would impose on an applicant for registration and accreditation and upon an RA-HMB seeking renewal of its registration and accreditation. In addition, the proposed new rule would establish the manner by which the Department would calculate and impose travel costs that it incurs to conduct an onsite inspection of an entity that applies for registration and accreditation and upon an existing RA-HMB, and would identify the ways an entity can pay these costs. Proposed new N.J.A.C. 8:75-2.8, Cessation of operations; change in ownership, would establish standards by which an RA-HMB is to notify the Department if it intends to discontinue operations or transfer ownership to another entity, and would identify the procedure by which a proposed new owner is to apply for authorization to obtain registration and accreditation of the RA-HMB as a new owner, and procedures by which a proposed new owner could facilitate continuity of the RA-HMB's operations without interruption by applying to the DepartmentdDepartment for preapproval of the new ownership prior to the conclusion of the transaction (closing) on the transfer of ownership. Proposed new N.J.A.C. 8:75-2.9, Provisional registration and accreditation,

would establish a procedure by which an HMB that is presently operating in the State could apply for provisional registration and accreditation without interruption of existing operations upon the effective date of the proposed new rules, to facilitate the continuity of HMB services to existing clients who rely on a consistent supply of donor human milk (DHM) for vulnerable infants, pending the Department's issuance of a final determination on the HMB's application for registration and accreditation.

Subchapter 3, Administration; Policies and Procedures, would establish standards for administration of HMBs and identify required policies and procedures. Proposed new N.J.A.C. 8:75-3.1, Administrator qualifications and functions, would establish minimum credentialing and functional standards for RA-HMB administrators. Proposed new N.J.A.C. 8:75-3.2, Medical director qualifications and functions, would establish minimum credentialing and functional standards for RA-HMB medical directors. Proposed new N.J.A.C. 8:75-3.3, Medical advisory committee, would establish minimum standards for the establishment, functions, and member credentials of an RA-HMB's medical advisory committee. Proposed new N.J.A.C. 8:75-3.4, Required policies and procedures, would identify the policies and procedures that an RA-HMB is to establish through its administrator, in consultation with its medical director and medical advisory committee, which are to be founded upon evidence-based, peer-reviewed research and best practices. Proposed new N.J.A.C. 8:75-3.5, Maintenance of records, would establish RA-HMB recordkeeping requirements, and require an RA-HMB to retain the records for a period following final disposition of the DHM that is consistent with the health facility record retention requirements at N.J.S.A. 26:8-5 which is for a period of 10 years or until a patient reaches the age of 23 years, whichever is the longer time period, that is, the infant, reaches the age of 23 years is consistent with the record retention requirements that currently apply to health facilities. Proposed new N.J.A.C. 8:75-3.6, Reportable events, would identify occurrences that an RA-HMB is to report, and the manner and deadlines by which an RA-HMB is to report each type of event to the Department. Proposed new N.J.A.C. 8:75-3.7, Responsibility for delegated services, would identify the coextensive responsibility of an RA-HMB for the performance of HMB services that it may delegate to a third party.

Subchapter 4, Donor Selection and Training, would establish standards by which an RA-HMB is to perform selection and training of an HMB donor. Proposed new N.J.A.C. 8:75-4.1, Donor identification, screening, and qualification would establish donor identification, screening, and qualification standards. Subsection (a) would require an RA-HMB to issue a unique identifier to each potential DHM donor. Subsections (b) and (c) would require an RA-HMB to initially, and periodically thereafter, screen each donor for health and lifestyle conditions that would contraindicate the HMB's acceptance of DHM from that donor. Subsection (d) would require an RA-HMB to require a prospective donor to submit a written statement of the donor's healthcare professional and, if applicable, the healthcare professional of the donor's infant, identifying the appropriateness of a potential donor serving as a DHM donor given the risks to, and health and lifestyle conditions of, the donor and the donor's infant. Subsection (e) would identify the types and frequency of serological testing that an RA-HMB is to require a potential or accepted donor to undergo upon initial qualification to serve as a DHM donor and periodically thereafter. Subsection (f) would identify the serology test results that would require an RA-HMB to exclude the donor from donating DHM.

N.J.A.C. 8:75-4.1(g) would identify the factors an RA-HMB is to consider in determining whether to accept a potential DHM donor. Subsection (h) would require an RA-HMB to obtain a donor's informed consent to the RA-HMB's use of the donor's DHM to perform HMB services and to the RA-HMB's retention of records in accordance with proposed new N.J.A.C. 8:75-3.5. Subsection (i) would require an RA-HMB to require its donors to notify the RA-HMB upon the occurrence of events or conditions that temporarily or permanently would contraindicate the RA-HMB's use of the donor's DHM to perform HMB services. Subsection (j) would require an RA-HMB to evaluate information about a donor that it receives pursuant to proposed new subsection (i) and determine an appropriate responsive action to take, such as to require the donor to undergo additional serological testing, and/or defer temporarily or exclude permanently its further acceptance of DHM from that donor. Subsection (k) would identify an RA-HMB's recordkeeping responsibilities with respect to its donor screening activities.

Proposed new N.J.A.C. 8:75-4.2, Donor exclusion and deferral criteria, at subsections (a) and (c), would establish conditions requiring the mandatory temporary deferral or permanent exclusion of donors. These criteria include those intended to detect infectious disease risk, such as incarceration, which due to congregate living conditions, the possibility of unprotected sex with multiple partners while incarcerated, the sharing of needles by some inmates to inject drugs, and the use of makeshift equipment by inmates for body tattooing result in an increased risk for infectious disease for recently incarcerated individuals and their sexual partners. Subsection (b) would authorize an RA-HMB to impose more stringent deferral or exclusionary criteria than those listed in the section. Subsection (d) would require an RA-HMB to exercise its obligation to defer or exclude donors due to consumption of certain medications or other substances in consideration of its policies and procedures. Subsection (e) would identify certain factors an RA-HMB is to consider in developing and implementing the protocol it would apply pursuant to subsection (d). Subsection (f) would require an RA-HMB periodically to review and update the protocol it establishes pursuant to subsection (d).

Proposed new N.J.A.C. 8:75-4.3, Donor education program, at subsections (a) and (b), would require an RA-HMB to establish a donor education program, administer it to each donor before accepting DHM from a donor, and ensure that the donor comprehends the instruction. Subsection (c) would identify the minimum content and subject matter that an RA-HMB is to address in its donor education program.

Subchapter 5, Collection of DHM, would address DHM collection. Proposed new N.J.A.C. 8:75-5.1, Collection of DHM, at subsection (a), would require an RA-HMB to collect DHM in accordance with its policies and procedures and consistent with evolving best practices and applicable Federal standards. Subsection (b) would require an RA-HMB to collect DHM only from qualified donors. Subsection (c) would require an RA-HMB to obtain each donor’s informed consent and provide pre-labeled sterile, leakproof containers and seals to each donor, which the donor would use to collect and store DHM. Subsection (d) would prohibit an RA-HMB’s use of DHM that was heated or improperly stored prior to the RA-HMB’s collection thereof. Subsection (e) would

require an RA-HMB to maintain records as to its method of DHM collection from a donor.

Subchapter 6, Storage of DHM, would address DHM storage. Proposed new N.J.A.C. 8:75-6.1, Storage of DHM, would require an RA-HMB to store DHM in accordance with its policies and procedures and consistent with evolving best practices and applicable Federal standards, including the AAP Storage Recommendations.

Subchapter 7, Processing DHM, would address DHM processing. Proposed new N.J.A.C. 8:75-7.1, Processing DHM, would require an RA-HMB to process DHM in accordance with its policies and procedures and consistent with evolving best practices and applicable Federal standards, and maintain records of processing activities, batch composition, and pathogen testing.

Subchapter 8, Distribution of DHM, would address DHM distribution. Proposed new N.J.A.C. 8:75-8.1, Distribution of DHM, at subsection (a), would require an RA-HMB to distribute DHM in accordance with its policies and procedures and consistent with evolving best practices and applicable Federal standards. Subsection (b) would require an RA-HMB, in distributing DHM directly to a parent, to issue a written statement of the risks of an infant's consumption of DHM in the parent's language, and to ensure that the parent comprehends the notice. Subsection (c) would require an RA-HMB to maintain records of its distribution activities.

Subchapter 9, Enforcement Actions and Hearings, would address enforcement actions and hearings. Proposed new N.J.A.C. 8:75-9.1, Enforcement actions, would establish standards and procedures for Department actions against an HMB's registration and accreditation. Subsection (a) would address summary suspension. Subsection (b) would address suspension and revocation, issuance of a formal written action, and denial of issuance or renewal. Subsections (c), (d), and (e) would address imposition of monetary penalties in accordance with N.J.S.A. 26:2A-21. Subsection (f) would address sanctions for delinquency in payment of monetary penalties. Proposed new N.J.A.C. 8:75-9.2, Hearings, would establish procedures by which an entity against which the Department is imposing an enforcement action can seek a hearing, and procedures for the conduct of hearings. Proposed new N.J.A.C. 8:75-9.3, Enforcement against operation without Department registration and accreditation, would reiterate the

Department's authority, pursuant to N.J.S.A. 26:2A-21, to seek injunctive relief and impose monetary penalties against, and refuse to issue registration and accreditation to an entity that operates an HMB or provides HMB services without first obtaining Department registration and accreditation.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The AAP has determined that "[b]reastfeeding and human milk are the normative standards for infant feeding and nutrition. The short- and long-term medical and neurodevelopmental advantages of breastfeeding make breastfeeding, or the provision of human milk, a public health imperative. The … AAP … recommends exclusive breastfeeding for approximately [six] months after birth." (2). The AAP "recommends pasteurized [DHM] when a mother's milk is not available or is contraindicated." *Id.*; (1) (Department Note: numbers in parentheses that follow correspond to the list of references that appear following the last statement). The AAP further finds that while an infant's lactating parent's "own milk is always preferred," DHM "can be beneficial to supplement the mother's own milk when necessary. The evidence to support the use of donor human milk has been reviewed, and recent studies … support health benefits for its use in infants with a birth weight [under 1,500 grams], especially in decreasing rates of necrotizing enterocolitis. Donor milk banks represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in [neonatal intensive care units (NICUs)] and other settings." (1)

The proposed new rules would provide a pathway through which parents of eligible infants can obtain DHM that an RA-HMB has collected from appropriately screened donors, and processed, stored, and distributed in accordance with safety and sanitary protocols to prevent transmission of disease. Absent the availability of DHM from an RA-HMB, parents of these infants may resort to obtaining DHM through less safe and reliable sources of DHM, such as informal milk sharing or internet purchasing.

In this regard, the AAP notes that "accessibility to donor milk in the United States continues to be substantially limited in terms of supply, cost, and distribution. As of

these limitations, some parents have chosen to exchange human milk that is not pasteurized or handled by an established milk bank with each other (milk sharing)." *Id.* The AAP, and the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) of the United States Department of Health and Human Services, all recommend against obtaining human milk through informal milk-sharing and internet purchase as being unsafe. For example, the AAP states, "informal direct milk sharing without pasteurization exposes infants to a range of possible risks, including bacterial contamination and viral transmission, including cytomegalovirus, hepatitis viruses, and HIV. Individual screening is performed by some Internet-based groups that organize direct milk sharing, but these are neither consistently applied nor documented. Furthermore, even with serologic blood testing, infectious complications remain a significant risk in unpasteurized milk." *Id.*

Likewise, the FDA states that, in feeding an infant human milk from a source other than an infant's lactating parent, "[r]isks for the baby include exposure to infectious diseases, including HIV, to chemical contaminants, such as some illegal drugs, and to a limited number of prescription drugs that might be in the human milk, *if the donor has not been adequately screened*. In addition, *if human milk is not handled and stored properly,* it could, like any type of milk, become contaminated and unsafe to drink. [The] FDA recommends against feeding [a] baby breast milk acquired directly from individuals or through the Internet. When human milk is obtained directly from individuals or through the Internet, the donor is unlikely to have been adequately screened for infectious disease or contamination risk. In addition, it is not likely that the human milk has been collected, processed, tested or stored in a way that reduces possible safety risks to the baby." (15) (emphasis added)

The proposed new rules may have a beneficial physical and psychological impact on adoptive and gender-diverse parents and their infants by facilitating a safe supply of donor human milk when the milk of an infant's delivering parent is not available. (4) The availability of safe DHM also may provide mental health benefits to parents who cannot provide their own milk for other reasons. A study of parents in the United Kingdom who had low or no supply of their own milk, due to cancer, bilateral mastectomy, or other health reasons of the parent or the infant, found that receiving

DHM with lactation support from a community-facing milk bank was associated with a significant decrease in anxiety and depression scores. (8 and 9)

Lactating parents bereaving a perinatal loss may realize physical and psychological benefits through the availability of RA-HMBs to which they can donate their unneeded human milk, such as by relief of the physical pain of engorgement, as a means of processing their grief, and by obtaining the satisfaction of knowing their altruistic act of donation will help preserve the life or health of another parent's infant. (21, 22, and 27)

The proposed new rules may create greater awareness of the availability of, and the safety, health benefits, and cultural acceptability of using DHM from RA-HMBs when an infant's delivering parent's milk is unavailable. This, in turn, may increase the use of DHM instead of formula among various racial and ethnic groups who are underrepresented among DHM consumers, despite the known benefits associated with its use. Systemic efforts to raise awareness of the availability, and benefits associated with the use, of DHM through RA-HMBs could increase the number of infants who obtain access to this resource. For example, the AAP reports that "[r]acial and ethnic disparities in the provision of mother's milk and pasteurized donor milk for … infants [of very low birthweight] are well-described; human milk use is lower among … infants [of very low birthweight] with non-Hispanic Black mothers, compared with those with non-Hispanic White mothers." (23)

The AAP, among other recognized authorities, recommends exclusive breastfeeding for at least the first six months of an infant's life. (2 and 3) The availability and use of DHM and HMBs to supplement the milk supply of an infant's delivering parent "complements other strategies to support breastfeeding" and has been associated with "higher rates of breastfeeding beyond delivery, even for infants who are admitted to neonatal intensive care units." (26)

For example, in "a study of 83 neonatal intensive care units in Italy … the prevalence of exclusive breastfeeding at discharge was 14 percentage points higher in the units with a human milk bank than in those without. And, in the US, a small study of 122 infants [hospitalized] for the treatment of hypoglycemia, hyperbilirubinemia, and [greater than eight percent] weight loss at 40 hours of life found that newborns who

received donor breast milk had five times greater odds of exclusive breastfeeding at [six] months old compared with those who received formula." *Id.* While "[e]xcessive [animal-based] formula use" in hospitals "interferes with the establishment of lactation and is associated with a four-fold higher risk of breastfeeding cessation by [two] months," a study of northeastern United States hospitals found that hospitals that made available and used DHM "for healthy newborns had higher exclusive breastfeeding at hospital discharge than hospitals that did not (77 [percent] versus 56 [percent])." (7)

The Department is unaware of entities that would realize a negative social impact because of the proposed new rules.

Economic Impact

The following would incur costs associated with the proposed new rules: the Department, persons seeking to establish an RA-HMB, existing HMBs applying to be RA-HMBs, RA-HMBs, hospitals, and prospective and qualified DHM donors.

The Office of Legislative Services (OLS) found that the Act (and, thus, upon Department implementation through the proposed new rules) would cause the State to realize "additional recurring State expenditures associated with processing applications for registration of [HMBs] and conducting inspections. These costs would be offset by additional recurring State revenues from registration-related fees and penalties[, but] the magnitude of such expenditures and revenues cannot be determined due to uncertainties regarding the [Department's] implementation of the [Act] and the number of [HMBs] that [would] be subject to the [Act's] provisions. The [Act] requires an annual registration fee established by the [Department] to offset its administrative costs in executing the [Act], so the [Act] is designed to be cost-neutral. In the short term, uncertainty about the number of applicants could make it difficult to appropriately calibrate the fee amounts and administrative spending, but over time the OLS expects that the registration program will be financially self-sustaining[, noting that according to HMBANA,] there are no [HMBs] with physical locations in or under development in New Jersey as of February 2017. However, [HMBs] located in other states that distribute [DHM] in New Jersey would be subject to the [Act's] requirements. The OLS does not know how many out-of-State milk banks may seek accreditation and registration under the [Act]." S974(1R), Fiscal Estimate (2017).

The Department concurs with this assessment, having no knowledge as to the number of in-State or out-of-State entities that would apply for registration and accreditation or the total revenues the Department might realize from fees and penalties upon the Department's promulgation and implementation of the proposed new rules.

The Department would incur ongoing operational and administrative costs associated with filling and retaining four new staff positions; purchasing, and ongoing maintenance of infrastructure, such as information technology resources; performing reviews of applications for initial and annual renewal of registration and accreditation, annual assessments, and on-site inspections of proposed HMBs and RA-HMBs at least once every five years; and conducting ongoing oversight and enforcement activities. The Department estimates that it will cost from $250,000 to $300,000 annually to operate the HMB component of the Biobanking Compliance Program for salaries at current Civil Service Commission rates, infrastructure, and administrative and travel expenses.

As the OLS Fiscal Estimate recognizes, revenues associated with fees and penalty assessments cannot be determined because it is impossible to predict the number of entities that will apply to be RA-HMBs, the number of entities that will incur penalties due to noncompliance with the Act and/or the proposed new rules, and the extent to which revenues recovered therefrom would offset the Department's operational costs. Therefore, the proposed fee of $1,500 for initial, and annual renewal of, registration is an interim figure until the Department has greater certainty as to its annual expenses and revenues. Upon having greater experience over time as to the operation of the HMB component of the Biobanking Compliance Program, the Department would then be able to adjust the fee *pro-rata* among regulated entities through a future rulemaking. While the proposed $1,500 fee would probably be insufficient to cover the Department's operational costs, at least in the Biobanking Compliance Program's first year, imposing the Department's actual operating costs on entities that apply for registration and accreditation during the first year of the program's operation might be cost-prohibitive to some members of the regulated community and thus deter desired RA-HMB activity in the State. The Department notes that the proposed fee is reasonable in comparison to, and competitive with, other states that

assess fees to regulate HMBs in their states. For example, the license fee in California is $975.00; in Pennsylvania, the initial license fee is $1,000, and the renewal fee is $250.00.

An applicant for initial registration and accreditation as an RA-HMB would incur costs associated with readying the premises of a proposed HMB to comply with FDA and/or accrediting body standards, which would vary depending on which HMB services (collection, processing, storage, marketing, and/or distribution) the entity proposes to perform, but would likely include the costs of owning or leasing premises and equipment (plus utilities and taxes) and retaining personnel; administrative expenses associated with preparation and submission of an application; and the application fee. In addition to these costs, following initial registration and accreditation, an RA-HMB would incur ongoing operational costs associated with obtaining materials and services to undertake facility and equipment maintenance, laboratory testing, packaging for collection of DHM and distribution after processing, distribution such as courier services, and recordkeeping. Other than payment of Department fees for initial issuance and annual renewal of registration and accreditation, the Department expects that an existing HMB currently operating in the State already incurs the costs listed above that it would incur to comply with the proposed new rules, because it is pursuant to existing obligations pursuant to Federal law and/or accrediting body standards to comply with these standards. An HMB that operates without obtaining Department registration and accreditation or otherwise fails to comply with the Act or the proposed new rules would incur costs associated with Department enforcement actions, such as a penalty assessment, lost income due to suspension or revocation, and legal services retention to defend against enforcement action.

A parent of an infant who requires and is eligible to obtain PHM from an RA-HMB is likely to realize cost savings by the Department's adoption of the proposed new rules. P.L. 2017, c. 309, requires various entities that pay for hospital or medical benefits doing business in the State (such as health insurers) to provide coverage for PHM upon the order of a licensed medical practitioner if an infant under six months of age has a body weight below healthy levels, a congenital or acquired condition that places the infant at high risk for development of necrotizing enterocolitis, or a congenital or

acquired condition that may benefit from the use of DHM. For infants in the same circumstances, P.L. 2019, c. 317, codified in part at N.J.S.A. 30:4D-6, and subject to the Commissioner of the Department of Human Services obtaining necessary amendments or waivers with respect to the State Medicaid plan and promulgating necessary implementing rules (see P.L. 2019, c. 317, §§ 2 through 4), requires Medicaid coverage for PHM, provided the milk is obtained from an HMB "that meets quality guidelines established by the Department." Thus, the proposed new rules would enable a parent whose infant is in these circumstances to avoid paying out-of-pocket for PHM. "Without … insurance coverage, cost per infant (using [PHM]) could reach up to $1,050 per week, which is a significant barrier to access to [PHM] milk for most families." (6)

However, anecdotal information and various studies indicate that hospitals incorporate the cost of providing PHM into their operational budgets "in recognition of its financial value toward an exclusive human milk diet during the initial hospital stay after birth." (24) The proposed new rules would enable hospitals to receive reimbursement for the costs they incur to provide PHM to infants in their care who have the health conditions listed above, instead of having to absorb these costs into their operational budgets.

As the Social Impact describes, use of PHM in caring for infants who are preterm and/or of very low birth weight has been shown to improve feeding tolerance and allow quicker weight gain, and decrease the rates of necrotizing enterocolitis by approximately two-thirds compared with the use of formula, with corresponding reductions in complications associated with that illness (such as sepsis), prolonged hospitalization, the need for surgical intervention, and permanent long-term health impairments. (6) Most studies agree that costs associated with necrotizing enterocolitis in the United States can be "astronomical," because infants with necrotizing enterocolitis can require approximately 18 days of additional hospital stay, and infants with necrotizing enterocolitis who require surgery might spend up to 50 more days in the hospital compared with infants without necrotizing enterocolitis. *Id.* Savings realized from avoidance of necrotizing enterocolitis increase when long-term societal costs are considered, such as the costs of specialized health care and education, housing, loss of productivity, and reduced lifetime earnings for infants in whom necrotizing enterocolitis

causes permanent or long-term impairments; and lost wages and productivity incurred by family members who provide care to these infants. *Id.* While all studies of the economic impact of the use of DHM show cost-effectiveness and cost savings, estimates of these savings vary, based on such factors as the economic evaluation model used and the study time range. (28)

Health insurers and State government assistance programs, such as the New Jersey Supplemental Nutrition Program for Women Infants and Children (commonly known as WIC) and Medicaid, would incur costs associated with providing reimbursements to parents and hospitals for expenses they incur to obtain and provide PHM to infants who have qualifying health conditions. These entities would realize cost savings resulting from the avoidance of costs associated with treatment and hospitalization of infants for necrotizing enterocolitis and related complications.

Depending on the reimbursement and compensation policies of RA-HMBs, prospective and qualified donors of DHM may incur costs associated with obtaining written statements from health care providers as to the health of the donor and, if applicable, the donor's infant; obtaining required initial and repeat serologic screening; losing personal or professional productivity due to the time needed to express DHM and deliver it to an RA-HMB; and mileage or other expenses associated with travel to deliver DHM to RA-HMB collection stations. Persons who donate DHM to an RA-HMB that compensates donors would realize an economic benefit from their donations, at the rate of a dollar or so per ounce of DHM.

Federal Standards Statement

The FDA has established standards to regulate "establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps)" and standards for HCT/P "donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by [HCT/Ps]," but specifically excludes human milk from the definition of an HCT/P. 21 CFR 1271.1(a) and 1271.3(d)(3).

The FDA has yet to establish standards regulating DHM or HMBs. (14) However, in the Consolidated Appropriations Act of 2023, Congress directed the FDA

"to address regulation of donor human milk and donor human milk derived products and banks." (17)

Manufacturers and distributors of food that is introduced into interstate commerce must comply with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 et seq. (FDA Act), and the implementing regulations at 21 CFR Chapter I (§§ 1 through 1299) (FDA Code). This includes manufacturers of "infant formula" and "exempt infant formula" (described below). 21 CFR 106.3 defines "infant formula" to mean "a food [that] purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." The FDA uses the term, "infant formula," to mean a food that is intended for consumption by healthy, full-term infants.

The FDA Act and FDA Code require infant formula manufacturers to register with the FDA, and to adhere to standards relating to nutrient content and quantity specifications, nutrient quality control procedures, current good manufacturing practices, testing, labeling, recordkeeping, reporting, conduct of audits, prevention of adulteration, and traceability (such as for recalls). 21 U.S.C. § 350a and see (14). The FDA intends its standards for regular infant formula "to help ensure the consistent production of safe and nutritionally adequate infant formulas for consumption by healthy, [full-term] infants." FDA Exempt Infant Formula Guidance at 4. The FDA deems infant formula that is manufactured without adherence to these standards (unless it is "exempt infant formula," described below) to be "adulterated" and/or "misbranded," in violation of the FDA Act and the FDA Code, and subject to FDA enforcement action, which can include mandatory recall if the FDA determines that the product presents a risk to human health. 21 U.S.C. § 350a.

The FDA defines an "exempt infant formula" to mean "an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems" 21 CFR 107.3. The FDA recognizes "that exempt infant formulas may need to differ from non-exempt infant formula, [such as] in nutrient content due to the specific medical condition for which the exempt infant formula is used," but otherwise, the FDA requires exempt infant formula manufacturers to adhere

to the other standards that apply to the manufacture and distribution of non-exempt infant formula, "to the extent practicable." FDA Exempt Infant Formula Guidance at 5.

The FDA provides the following list of examples of exempt or "specialty" formula, which typically are unavailable in retail settings and may require a prescription:

> "[1] Hypoallergenic formulas with extensively hydrolyzed protein that are effective for the treatment of milk protein allergy. In these formulas, the protein has been broken down so that it can be more easily digested.
>
> [2] Formulas to treat a specific medical condition such as an inborn error of metabolism. For example, a formula for individuals with Phenylketonuria (PKU) does not contain the amino acid phenylalanine.
>
> [3] Infant formulas for premature infants, which may include more nutrients and calories to meet their increased nutritional needs.
>
> [4] Amino-acid-based formulas, which contain amino acids as their protein source. These formulas can be used for infants with severe milk allergies, short-gut syndrome, or other medical conditions."

(14)

To the Department's understanding, the Human Milk Bank Association of North America (HMBANA) conditions membership in HMBANA and HMBANA accreditation to HMBs that operate on a not-for-profit basis and exclusively accept milk from uncompensated donors, and HMBANA members limit the HMB services they perform to collecting, processing (pasteurization and testing), and distributing DHM, without additives or nutrient fortification. Therefore, as HMBANA members do not add fortifiers to, or otherwise modify DHM beyond processing, the FDA does not presently regulate DHM from HMBANA-accredited HMBs as a "food" under its jurisdiction, and the FDA's standards for infant formula and exempt infant formula would not apply to HMBANA-accredited facilities.

However, HMBANA's accrediting standards and processes appear to track the FDA standards applicable to infant formula and exempt infant formula manufacturing and distribution establishments. (Note: the Department does not have full access to HMBANA's HMB standards; "The complete version of HMBANA Standards for Donor Human Milk Banking is proprietary and is provided to each HMBANA-accredited member milk bank, along with accreditation documents and other tools.") (16) For example, HMBANA states that "HMBANA accreditation provides evidence that a milk bank is compliant with HMBANA Standards and maintains a comprehensive system of preventive controls, safety checks, verifications, validations, and corrective actions. HMBANA accreditation audits consist of onsite inspections, plant walkthroughs, record audits, standard operating procedure … and food safety plan review, sanitation assessments, staff training evaluations, mock recalls, critical control point audits, staff interviews, and additional rigorous safety evaluations. HMBANA auditors are certified preventive controls qualified individuals (PCQIs) … and receive additional auditor training on an annual basis." *Id.*

Inasmuch as the HMBANA standards appear to correspond to the FDA standards that apply to infant formula manufacturing, the proposed new rules would establish a procedure by which the Department would deem an entity that is HMBANA-accredited as qualifying for Department registration and accreditation, following application and track record review, including consideration of an HMB's HMBANA accreditation record, provided the HMB maintains its HMBANA accreditation in good standing, which may include timely and full compliance with an HMBANA-approved or directed plan of correction. Upon the FDA's implementation of Congress's mandate that it regulate DHM and HMBs, and given the FDA's express rejection of regulation of human milk as an HCT/P, it appears likely that the FDA will regulate DHM and HMBs in the same manner in which it regulates infant formula, that is, as a human food. Several bills have been introduced in Congress that, if passed, would require the FDA to regulate DHM. See, for example, the "Access to Donor Milk Act of 2023," which was concurrently introduced in both houses of Congress on September 14, 2023. H.R. 5486 and S. 2819 (2023). The Department anticipates that HMBs that operate pursuant to

HMBANA accreditation standards should be able to seamlessly demonstrate compliance with FDA standards when they become applicable to HMB's operations.

The Department is aware of at least one for-profit HMB that manufactures and distributes an FDA-recognized exempt infant formula that uses DHM as a base to which it adds nutritional fortifiers or applies other modifications for the needs of the infant population that uses it. This HMB, therefore, is subject to compliance with FDA standards applicable to exempt infant formula manufacturers. (12) As noted above, an HMB that operates for profit (and/or compensates donors) is ineligible for HMBANA accreditation.

In addition, an entity that produces an exempt infant formula can also be subject to FDA regulation of the product as a "medical food." The Orphan Drug Act, Pub. L. 97-414 (January 4, 1983), defines a "medical food" to mean a food that "is formulated to be consumed or administered enterally [(that is, directly to the digestive tract such as through a tube)] under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 21 U.S.C. § 360ee(b)3; 21 CFR 101.9(j)(8).

Medical foods can include exempt infant formulas that are fed enterally to infants with inborn errors of metabolism. "Inborn errors of metabolism include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. As a result of diminished or absent enzyme activity in these disorders, certain compounds accumulate in the body to toxic levels, and levels of other compounds that the body normally makes may become deficient … Without appropriate and accessible management, these metabolic disturbances can lead to a host of medical and developmental consequences ranging from intellectual disability to severe cognitive impairment and even death. Management may include one or a combination of the following: drug therapy, modification of the normal diet, or use of a medical food." (Internal citation omitted.) "Guidance for Industry: Frequently Asked Questions About Medical Foods; Third Edition" (March 15, 2023) at 8-9 (hereinafter referred to as "Medical Foods FAQs"), available at

https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/medical-foods-guidance-documents-regulatory-information.

In addition, an exempt infant formula that is fed enterally to a preterm infant or an infant of very low birth weight may also qualify as a medical food. As these infants are born with incomplete organ development, including the intestinal tract, "early enteral feeding is the preferred method of nutrient provision for preterm infants and low birth weight infants"; "early initiation of enteral feeding within the first 72 hours of life likely decreases the risk of neonatal mortality and may reduce the risk of sepsis when compared with delayed feeding initiation after 72 hours"; and "early initiation and more rapid enteral advancement, impact preterm infant health during the first one month of life by enhancing micronutrient delivery, promoting intestinal development and maturation, stimulating microbiome development, reducing inflammation, and enhancing brain growth and neurodevelopment." (25) Moreover, early initiation of enteral feeding is associated with a reduced length of an infant's hospital stay and is "linked to reduced risk of mortality and sepsis." (10)

FDA regulation of medical foods production, labeling, and distribution is consistent with its regulation of exempt infant formula. See Medical Foods FAQs at 8-9, and footnote 6. Thus, if an HMB produces DHM-based infant formula or exempt infant formula that is for enteric use, which the FDA recognizes as a medical food, the proposed new rules would meet, but not exceed, the FDA standard applicable to medical foods.

A nationwide infant formula shortage, which began during the COVID-19 pandemic, was worsened beginning in February 2022 upon an infant formula manufacturer's product recall and manufacturing facility closure, due to evidence of contamination with *Cronobacter sakazakii*, after four infants became ill, two of whom died. (2) *Cronobacter sakazakii* is a pathogenic bacterium that can cause bloodstream (such as sepsis) and central nervous system (such as meningitis) infections. (11) Complications of this infection in infants under two months old and preterm infants can include brain abscess, developmental delays, motor impairments, and death. *Id.*

The Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023, in response to these shortages and

illnesses, amended the FDA Act by directing the FDA to establish an “Office of Critical Foods” and to require manufacturers of “critical foods” (which means an infant formula or a medical food) “to develop, maintain, and implement, as appropriate, a redundancy risk management plan.” 21 U.S.C. §§ 321(ss), 350a-1(b), and 350m(b). In addition, on September 28, 2023, the FDA updated its infant formula compliance program manual, which outlines the procedures by which FDA inspectors, laboratory analysts, and compliance officers will implement FDA inspections, sample collection, sample analysis, and compliance activities. (13) The FDA will evaluate members of the regulated community that are subject to the FDA standards for infant formula, exempt infant formula, and DHM-based medical foods in accordance with this compliance program. In contrast to the rate at which it inspects non-critical food manufacturing facilities, which is at approximately three-year intervals, infant formula manufacturing facilities are subject to annual FDA inspections that are “robust, thorough, and focused on the most critical aspects of the infant formula manufacturing process.” (14)

The proposed new rules would condition Department registration and accreditation on compliance with applicable Federal standards as a minimum standard. Therefore, the proposed new rules would meet, but not exceed,a the FDA standards described above that apply to an HMB’s activities. There are no Federal standards for human milk donor screening, constitution of a medical advisory committee, or hiring a medical director; therefore, a Federal standards analysis is not required with respect to these aspects of the proposed new rules.

Except as described above, the Department is proposing this rulemaking pursuant to the authority at N.J.S.A. 26:2A-22 and not pursuant to the authority of, or to implement, comply with, or participate in, any program established pursuant to Federal law or a State law that incorporates or refers to any Federal law, standard, or requirement. Therefore, an additional Federal standards analysis is not required.

Jobs Impact

The Department anticipates that the proposed new rules would result in the creation of jobs by entities seeking to operate human milk banks or distribute donated human milk in the State for persons to perform administrative functions associated with registration and recordkeeping for human milk banks, and for operational functions

associated with the collection, processing, storage, marketing, and/or distribution of human milk. The Department is unable to estimate the number of jobs because the registration of human milk banks is a new State initiative and the Department does not know the number of entities that would apply for registration and accreditation, the size of those entities, or the HMB services they would seek authorization to perform. The proposed new rules might support the existing demand for personnel at healthcare facilities, such as neonatal intensive care units in hospitals, that currently use existing staff to perform functions associated with the provision of HMB services at those facilities.

As the Economic Impact describes, the Department's implementation of the Act and the proposed new rules would require the Department to retain staff with administrative and subject matter expertise to perform functions associated with accepting and processing applications for registration and accreditation, periodically reviewing and updating accreditation standards and the implementing rules, as necessary, to ensure that registrants adhere to the latest and most effective best practices to protect public health, conducting onsite inspections of registrants, and pursuing enforcement activities against entities that are not compliant with the Act and the proposed new rules. The Department does not anticipate that the proposed new rules would result in the loss of jobs in the State.

Agriculture Industry Impact

The Department does not anticipate that the proposed new rules would have an impact on the agriculture industry of the State.

Regulatory Flexibility Statement

The proposed new rules would impose requirements applicable to entities seeking to apply for, and annually renewing, Department registration and accreditation as human milk banks in the State. The Department is unable to estimate the number of entities that would seek to become registered human milk banks in the State or the number of such entities that would be small businesses within the meaning of the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., because the registration and accreditation of these facilities is a new State initiative. Hospitals that the Department licenses pursuant to the Health Care Facilities Planning Act, N.J.S.A.

26:2H-1 et seq., that may operate human milk banks as part of their neonatal intensive care units are not small businesses within the meaning of the New Jersey Regulatory Flexibility Act.

To the extent the proposed new rules might apply to small businesses, the following analysis applies. The proposed new rules would impose reporting, recordkeeping, and other compliance requirements on entities that apply for and maintain Department registration and accreditation in the State. The Summary describes those requirements. The Economic Impact describes the costs of compliance. The Department anticipates that the proposed new rules would require registrants to retain the services of professionals with expertise in the operational functions associated with the collection, processing, storage, marketing, and/or distribution of human milk. The Department is unable to estimate the costs associated with retaining these professionals. The Department proposes no lesser or differing standards for small businesses because the Department has determined that the proposed new rules would establish the minimum standards necessary to ensure the safe and sanitary operation of human milk banks and distribution of donated human milk in the State as necessary to ensure public health.

Housing Affordability Impact Analysis

The proposed new rules would have no impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that they would evoke a change in the average costs associated with housing because the proposed new rules would establish standards for registration and accreditation of HMBs and would have no bearing on housing costs.

Smart Growth Development Impact Analysis

The proposed new rules would have no impact on smart growth, and there is an extreme unlikelihood that the proposed new rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan in New Jersey because the proposed new rules would establish standards for registration and accreditation of HMBs and would have no bearing on smart growth or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

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Full text of the proposal follows:

CHAPTER 75

HUMAN MILK BANK REGISTRATION AND ACCREDITATION

SUBCHAPTER 1. GENERAL PROVISIONS

8:75-1.1 Purpose and scope

(a) The purpose of this chapter is to implement N.J.S.A. 26:2A-17 et seq.

(b) This chapter applies to:

1. Applicants for initial and renewal of registration and accreditation as human milk banks;

2. RA-HMBs; and

3. Entities that provide human milk bank services.

8:75-1.2 Definitions

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

“AAP guidance” means the publications set forth at N.J.A.C. 8:75-1.4.

“Accrediting body” means the Human Milk Banking Association of North America (HMBANA), for which the contact information is 4455 Camp Bowie Blvd., Suite 114-88, Fort Worth, TX 76107, website: https://www.hmbana.org.

“ALIS portal” means the online application website that the Department administers to process applications for initial and renewal of registration and accreditation of HMBs, which is accessible by:

1. Creating an account at, and logging into, the State website at www.nj.gov (“My New Jersey”);

2. Sending an email to clis.biobanking@doh.nj.gov, requesting access to ALIS to submit an HMB registration and accreditation application, which will respond with a request for the applicant's preliminary contact information (name, address, telephone number, and electronic mail address, of the applying person and entity); and

3. After providing the requested preliminary contact information, entering the code the ALIS issues into the applicant's My New Jersey account, following which the applicant will obtain access to the ALIS application.

"American Academy of Pediatrics" or "AAP" means the American Academy of Pediatrics.

"Applicant" means an entity seeking issuance or renewal of RA-HMB status.

"Biobanking Compliance Program" or "BCP" means the Biobanking Compliance Program within CLIS for which the contact information is:

Biobanking Compliance Program, CLIS

New Jersey Public Health, Environmental, and Agricultural Laboratory

Mailing address for regular mail delivery:

PO Box 361, Trenton, NJ 08625-0361

Mailing address for courier service or in-person delivery:

3 Schwarzkopf Drive, Ewing, NJ 08628-1620

Electronic mail address: clis.biobanking@doh.nj.gov

"CDC" means the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"CDC breastfeeding guidance" means the publications and guidance documents set forth at N.J.A.C. 8:75-1.3(d).

"Clinical Laboratory Improvement Services" or "CLIS" means the Clinical Laboratory Improvement Services of the New Jersey Department of Health.

"Collection" means "collection" as defined at N.J.S.A. 26:2A-17.

"Commissioner" means the Commissioner of the Department of Health.

"Department" means the New Jersey Department of Health.

"Distribution" means "distribution" as defined at N.J.S.A. 26:2A-17.

“Donor” means a lactating person who contributes DHM to an RA-HMB, with or without compensation, for distribution to an ultimate consumer who is an infant other than the person’s own infant.

“Donor human milk” or “DHM” means human milk that a donor contributes to an RA-HMB and includes PHM.

“FDA” means the Food and Drug Administration of the United States Department of Health and Human Services.

“Healthcare professional” means a person who holds a license pursuant to Title 45 of the Revised Statutes as a physician, an advanced practice nurse, or a physician assistant.

“Human milk bank” or “HMB” means “human milk bank” as defined at N.J.S.A. 26:2A-17.

“Human milk bank services” or “HMB services” means:

1. Donor qualifications pursuant to N.J.A.C. 8:75-4;
2. Collection;
3. Processing;
4. Storage;
5. Marketing; and/or
6. Distribution.

“Injection drug use” means the administration of an illegal drug, such as heroin, cocaine, or methamphetamine, or a controlled substance, such as opioid pain relievers or stimulants, into the body using a needle and syringe.

“LactMed®” means the Drugs and Lactation Database established by the National Institutes of Health available at https://www.ncbi.nlm.nih.gov/books/NBK501922/.

“Marketing” means “marketing” as defined at N.J.S.A. 26:2A-17.

“Parent” means:

1. A biological parent;
2. An adoptive parent;
3. A “resource family parent” as defined at N.J.S.A. 30:4C-26.4; or

4. A person or an entity serving as legal guardian of a minor pursuant to an applicable statute, court rule, court order, or duly executed delegation of parental rights.

“Pasteurized human milk” or “PHM” means DHM that has been pasteurized.

“Person” means “person” as defined at N.J.S.A. 26:2A-17.

“Plan of correction” means:

1. For an HMB that an accrediting body has accredited, a “plan of modification,” of which the accrediting body approves and the implementation of which the accrediting body oversees for compliance;

2. For an HMB that is not accredited by an accrediting body, an FDA-approved timeline and implementation plan to address issues or deficiencies noted in an FDA-issued “Notice of Official Action Indicated,” which the FDA oversees for compliance or, if applicable, a plan of correction to address an FDA-issued “Notice of Voluntary Action Indicated”; and

3. For an applicant for registration and accreditation, or an RA-HMB, a BCP-approved, or BCP-directed list or description of the measures the applicant or RA-HMB is to undertake to correct BCP-identified deficiencies and the schedule for completion of each aspect of the plan.

“Processed DHM” or “PHM” means DHM that has undergone processing.

“Processing” means “processing” as defined at N.J.S.A. 26:2A-17.

“Prospective donor” means a person who is applying to an RA-HMB to contribute DHM.

“Qualified donor” means a person whom an RA-HMB has screened and approved to donate DHM in accordance with N.J.A.C. 8:75-4.

“Recipient” means:

1. A hospital to which an RA-HMB distributes PHM for use by low-birthweight babies or new delivering parents with delayed lactation; or

2. 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.

“Registered and accredited HMB” or “RA-HMB” means an entity to which the Department issues a certificate of registration and accreditation as an HMB, in accordance with N.J.A.C. 8:75-2.

“Serological testing” means testing in accordance with the CDC and FDA recommendations provided in the following publications, incorporated herein by reference, as amended and supplemented, respectively listed for the following conditions:

1. Hepatitis B: Conners EE, Panagiotakopoulos L, Hofmeister MG, et al., “Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023,” MMWR Recomm Rep (March 10, 2023) 72 (No. RR-1):1–25, available at DOI: http://dx.doi.org/10.15585/mmwr.rr7201a1;

2. Hepatitis C: Cartwright EJ, Patel P, Kamili S, Wester C, “Updated Operational Guidance for Implementing CDC’s Recommendations on Testing for Hepatitis C Virus Infection,” MMWR Morb Mortal Wkly Rep (July 14, 2023) 72:766–768, available at DOI: http://dx.doi.org/10.1558, ava5/mmwr.mm7228a2;

3. Human immunodeficiency virus: CDC, “Technical Update for HIV Nucleic Acid Tests Approved for Diagnostic Purposes” (last updated May 16, 2023), available at https://stacks.cdc.gov/view/cdc/129018;

4. Human T-lymphotropic virus: FDA, “Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II): Guidance for Industry,” 85 FR 6957-6959 (February 6, 2020), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-serological-tests-reduce-risk-transfusion-transmitted-human-t-lymphotropic-virus-types-i-and-ii; and

5. Syphilis: Papp JR, Park IU, Fakile Y, et al., “CDC Laboratory Recommendations for Syphilis Testing, United States, 2024” MMWR Recomm Rep (February 8, 2024), 73 (No. RR-1):1–32, available at DOI: http://dx.doi.org/10.15585/mmwr.rr7301a1.

“Storage” means “storage” as defined at N.J.S.A. 26:2A-17.

“Track record” means an entity’s record of compliance with applicable laws and accreditation standards.

8:75-1.3 Federal standards and regulatory guidance documents

(a) The Department incorporates herein by reference applicable provisions at Title 21—Food and Drugs, of the U.S.C., especially:

1. Chapter 1—Adulterated or Misbranded Foods or Drugs (21 U.S.C. §§ 1 through 26);

2. Chapter 9—Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 through 399i), at:

i. Section 350a, Infant formulas;

ii. Section 350a-1, Protecting infants and improving formula supply;

iii. Section 350d, Registration of food facilities; and

iv. Section 360ee, Grants and contracts for development of drugs for rare diseases and conditions (contains definition of “medical food”); and

3. Chapter 27—Food Safety Modernization (21 U.S.C. §§ 2201 through 2252).

(b) The Department incorporates herein by reference applicable provisions at Title 21 Food and Drugs of the CFR, Chapter I—Food and Drug Administration, Department of Health and Human Services, specifically:

1. Subchapter A—General, specifically at:

i. Part 1—General Enforcement Regulations;

2. Subchapter B—Food for Human Consumption, specifically at:

i. Part 101—Food Labeling, specifically Subpart A—General Provisions, at § 101.9 Nutrition labeling of food;

ii. Part 105—Foods for Special Dietary Use, specifically Subpart B—Label Statements, at § 105.65 Infant foods;

iii. Part 106—Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications;

iv. Part 107—Infant Formula, specifically Subpart C—Exempt Infant Formulas, § 107.50 Terms and conditions;

v. Part 108—Emergency Permit Control;

vi. Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food;

vii. Part 113—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers;

viii. Part 114—Acidified Foods; and

ix. Part 117—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; and

3. Subchapter L—Regulations Under Certain Other Acts Administered by the Food and Drug Administration, specifically at:

i. Part 1240—Control of Communicable Diseases (§§ 1240.3 through 1240.95), provided, the terms, "milk" and "milk products," as used in this Part at 21 CFR 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption, mean DHM, especially as used with respect to pasteurization requirements.

(c) The Department incorporates herein by reference, as amended and supplemented, the following FDA publications:

1. "Breast Pumps" (March 16, 2018) (consumer guidance), available at https://www.fda.gov/medical-devices/consumer-products/breast-pumps (consumer pump guidance);

2. "Guidance Documents and Regulatory Information by Topic (Food and Dietary Supplements)," available at https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements;

3. "Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls," 83 FR 55551-55552 (November 6, 2018), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-staff-questions-and-answers-regarding-mandatory-food-recalls;

4. "Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports," 81 FR 22174-22175 (April 15, 2016) (FDA Exempt Infant

Formula Guidance), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production;

5. “Guidance for Industry: Frequently Asked Questions About Medical Foods; Third Edition” (March 15, 2023) (Medical Foods FAQs), available at https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/medical-foods-guidance-documents-regulatory-information;

6. “HACCP Principles and Application Guidelines” (February 25, 2022), available at https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines#execsum;

7. “Infant Formula Guidance Documents and Regulatory Information Guidance Material,” available at https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/infant-formula-guidance-documents-regulatory-information; and

8. “2022 FDA Food Code,” available at https://www.fda.gov/food/fda-food-code/food-code-2022.

(d) The Department incorporates herein by reference, as amended and supplemented, the following CDC guidance documents and publications, hereinafter collectively referred to as the “CDC breastfeeding guidance”:

1. “About Breastfeeding” (December 18, 2023), available at https://www.cdc.gov/breastfeeding/php/about/index.html;

2. “Breastfeeding Recommendations and Guidance” (December 27, 2023), available at https://www.cdc.gov/breastfeeding/php/guidelines-recommendations/index.html;

3. “Breastfeeding Special Circumstances” (February 23, 2024), available at https://www.cdc.gov/breastfeeding-special-circumstances/about/index.html, specifically the subtopics on that page, which address medical conditions and lifestyle activities that may contraindicate an RA-HMB’s acceptance and use of a donor’s DHM, and indicate conditions warranting exclusion or deferral of a donor;

4. “Breast Milk Storage and Preparation” (November 27, 2023), available at https://www.cdc.gov/breastfeeding/breast-milk-preparation-and-storage/handling-breastmilk.html; and

5. “Water, Sanitation, and Environmentally Related Hygiene (WASH): About Breast Pump Hygiene” (May 17, 2024), available at https://www.cdc.gov/hygiene/about/about-breast-pump-hygiene.html?CDC_AAref_Val=https://www.cdc.gov/hygiene/childcare/breast-pump.html.

8:75-1.4 AAP guidance

(a) The Department incorporates herein by reference, as amended, supplemented, and reaffirmed, the following AAP guidance documents (hereinafter collectively referred to as the “AAP guidance”):

1. Abrams S, Landers S, Noble, L, Poindexter, B, AAP Committee on Nutrition, AAP Section on Breastfeeding, and AAP Committee on Fetus and Newborn, “Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States,” *Pediatrics,* 2017;139(1) (January 2017), e20163440, available at https://publications.aap.org/pediatrics/article/139/1/e20163440/52000/Donor-Human-Milk-for-the-High-Risk-Infant, and https://doi.org/10.1542/peds.2016-3440;

2. Meek JY, Noble L, and AAP Section on Breastfeeding, “Policy Statement: Breastfeeding and the Use of Human Milk,” *Pediatrics,* 150(1) (July 2022), e2022057988, available at https://publications.aap.org/pediatrics/article/150/1/e2022057988/188347/Policy-Statement-Breastfeeding-and-the-Use-of, and https://doi.org/10.1542/peds.2022-057988;

3. Meek JY, Noble L, and AAP Section on Breastfeeding, “Technical Report: Breastfeeding and the Use of Human Milk,” *Pediatrics* (July 2022), e2022057989, available at https://publications.aap.org/pediatrics/article/150/1/e2022057989/188348/Technical-Report-Breastfeeding-and-the-Use-of, and https://doi.org/10.1542/peds.2022-0579892;

4. Parker MG, Stellwagen LM, Noble L, et al., AAP Section on Breastfeeding, Committee on Nutrition, Committee on Fetus and Newborn, “Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant,” *Pediatrics,* 148(5) (November 2021), e2021054272, available at

https://publications.aap.org/pediatrics/article/148/5/e2021054272/181366/Promoting-Human-Milk-and-Breastfeeding-for-the, and https://doi.org/10.1542/peds.2022-057989..;

i. See especially Table 4: Maximum Human Milk NICU Storage Recommendations ("AAP Storage Recommendations"); and

5. Sachs HC, and AAP Committee on Drugs, "Clinical Report: The Transfer of Drugs and Therapeutics into Human Breast Milk: An Update on Selected Topics," *Pediatrics*, 132(3) (September 2013), e796-e809, available at https://publications.aap.org/pediatrics/article/132/3/e796/31630/The-Transfer-of-Drugs-and-Therapeutics-Into-Human, https://doi.org/10.1542/peds.2013-1985, and http://pediatrics.aappublications.org/content/132/3/e796 and https://doi.org/10.1542/peds.2013-1985; reaffirmed May 2018, see *Pediatrics,* 142(3) (September 2018), e20181836, available at https://publications.aap.org/pediatrics/article/142/3/e20181836/38679/AAP-Publications-Reaffirmed-or-Retired and https://doi.org/10.1542/peds.2018-1836.

8:75-1.5 Waiver

(a) The BCP may waive any part of this chapter if the BCP determines that waiver would not:

1. Endanger the life of any person;

2. Endanger public health, safety, or welfare; or

3. Adversely affect the provision of human milk bank services.

(b) A person seeking a waiver of a requirement of this chapter shall apply to the BCP, in writing, in which the person shall state:

1. The nature of the waiver the person is requesting;

2. The citation to the rule that the person is requesting the BCP to waive;

3. The reasons for the waiver request, including a statement of the type and degree of hardship that the person would realize if the BCP were to decline to grant the waiver;

4. An alternative proposal that would ensure public safety; and

5. Documentation to support the waiver application.

(c) The BCP may request additional information before processing a waiver request.

SUBCHAPTER 2. ISSUANCE AND RENEWAL OF REGISTRATION AND ACCREDITATION; INSPECTION; FEES

8:75-2.1 Application for registration and accreditation; authorized HMB services

(a) A person seeking to operate an HMB and/or perform any HMB service in New Jersey shall apply to the BCP for registration and accreditation as an RA-HMB pursuant to the Act by submitting, either electronically through the ALIS portal or by regular mail to the BCP:

1. The information and documentation requested in the application form at NN.J.A.C. 8:75 Appendix, incorporated herein by reference;

2. If applicable, the information and documentation described at N.J.A.C. 8:75-2.2 and/or 2.3; and

3. The nonrefundable fee and, if requested, BCP travel expenses, specified at N.J.A.C. 8:75-2.7.

(b) An applicant shall indicate in the application:

1. The HMB services that the applicant seeks BCP authorization to perform; and

2. If the HMB seeks BCP authorization to perform an HMB service at a location (“other authorized location”) other than the RA-HMB's principal place of business, the information and materials specified at (a) above for each proposed other authorized location.

i. Each proposed other authorized location is subject to review, inspection, and applicable fees as if the other authorized location were applying as an independent HMB for registration and accreditation.

(c) The BCP shall:

1. Notify an applicant, in writing, if it determines that an application is incomplete;

2. Identify, in the written notice, the information or material needed to complete the application; and

3. Refrain from processing the application until the applicant submits the information or material necessary to complete the application.

i. If the BCP does not receive, within 30 days of issuance of a notice issued pursuant to (c)2 above, the information or material that the notice

identifies as needed from the applicant to complete the application, the BCP will consider the applicant to have abandoned the application and the nonrefundable fees (without prejudice to the application being reactivated if the applicant submits the information or material indicated in the written notice and, absent the BCP granting an extension of the deadline by waiver pursuant to the process at N.J.A.C. 8:75-1.5, the resubmission of applicable fees); and

ii. Provisional RA-HMB status granted pursuant to N.J.A.C. 8:75-2.9 irrevocably lapses upon abandonment of an application.

(d) Upon finding that an application is complete, and an applicant has paid the applicable fee, the BCP will review the application in accordance with N.J.A.C. 8:75-2.2 or 2.3, as applicable, and may perform an onsite inspection of the premises pursuant to N.J.S.A. 26:2A-19 and N.J.A.C. 8:75-2.4.

8:75-2.2 Registration and accreditation criteria

(a) An applicant for Department registration and accreditation as an HMB shall submit the following with its application:

1. The information and documentation requested in the form of application at N.J.A.C. 8:75 Appendix;

2. The applicable fee as specified at N.J.A.C. 8:75-2.7;

3. A copy of the applicant's lease of or deed to the premises, and, if applicable, the certificate of occupancy;

4. If applicable, the report of the last inspection that the FDA, the State of New Jersey, a county, and/or a municipality performed, identifying deficiencies noted, the plan of correction that the FDA, the State of New Jersey, the county, and/or the municipality approved or directed, and a report of the status of the applicant's compliance with the plan of correction; and

5. For purposes of track record review, for each other HMB that the applicant and/or a subsidiary or parent of the applicant, owns or operates, in the State of New Jersey or another jurisdiction, if applicable:

i. The report of the last inspection that the FDA, the State of New Jersey, a county, a municipality, and/or another jurisdiction performed, identifying

deficiencies noted, the plan of correction that the FDA, the State of New Jersey, the county, the municipality, and/or the other jurisdiction approved or directed, and a report of the status of the HMB's compliance with the plan of correction.

(b) The BCP may conduct an onsite inspection of the premises at which an applicant proposes to perform HMB services in accordance with N.J.S.A. 26:2A-19 and N.J.A.C. 8:75-2.4.

(c) The BCP shall consider the following, as applicable, in determining whether to grant an application for RA-HMB status:

1. The result of the BCP's inspection of the proposed HMB premises;

2. The applicant's track record at the premises:

i. At which the applicant proposes to perform HMB services; and

ii. Of each HMB identified at (a) above.

(d) The BCP shall register and accredit an applicant if:

1. The application demonstrates that the premises, equipment, operational capacity, personnel (including the administrator, medical director, and medical advisory committee), and policies and procedures, are fit and adequate; and

2. The track record of the applicant's existing facility and the HMBs indicated at (a) above indicate that the applicant, and/or a subsidiary or parent of the applicant, is in compliance with N.J.S.A. 26:2A-17 et seq., this chapter, applicable Federal, State, and local regulatory standards in New Jersey and in other jurisdictions in which the applicant, and/or a subsidiary or parent of the applicant, performs HMB services; and

3. There is reasonable assurance that the applicant will operate the HMB in accordance with N.J.S.A. 26:2A-17 et seq., and this chapter.

8:75-2.3 Registration and accreditation by deemed status

(a) An applicant for Department registration and accreditation as an RA-HMB through deemed status shall submit the following to the BCP:

1. The information and documentation required pursuant to N.J.A.C. 8:75-2.2;

2. A certificate of accreditation that an accrediting body issued to the applicant that bears the seal of the accrediting body and identifies the effective dates of the accreditation;

3. The report of the last inspection and audit of the HMB that the accrediting body performed preceding the filing of the application, identifying, if applicable:

i. Deficiencies noted;

ii. A plan of correction that the accrediting body-approved or directed; and

iii. A report of the status of the applicant's compliance with the plan of correction; and

4. For purposes of track record review, for each other accredited HMB that the applicant and/or a subsidiary or parent of the applicant, owns or operates, in the State of New Jersey or another jurisdiction, if applicable, the report of the last inspection that the accrediting body performed, identifying deficiencies noted, the plan of correction that the accrediting body approved or directed, and a report of the status of the HMB's compliance with the plan of correction.

(b) The BCP shall review the applicant's record of accreditation, FDA, State, and local government inspections, compliance with approved and/or directed plans of correction, and track record in every jurisdiction in which the applicant, and/or a subsidiary or parent of the applicant, owns or operates an HMB, and shall register and accredit the applicant if the BCP determines that:

1. The application demonstrates that the premises, equipment, operational capacity, personnel (including the administrator, medical director, and medical advisory committee), and policies and procedures, are fit and adequate;

2. The applicant's existing HMB and track record indicate that the applicant is operating, and there is reasonable assurance that the applicant will continue to operate, in compliance with:

i. N.J.S.A. 26:2A-17 et seq., and this chapter;

ii. Applicable Federal, State, and local government standards;

iii. Applicable accrediting body standards; and

iv. Applicable Federal, State, local government, and accrediting body plans of correction.

8:75-2.4 Inspection

(a) In accordance with N.J.S.A. 26:1A-1 et seq., specifically, 26:1A-15, 16, 17, 18, and 19, and N.J.S.A. 26:2A-17 et seq., specifically at 26:2A-19, an applicant or an RA-HMB shall make available for inspection to the BCP, upon request, during normal operating hours and with or without prior notice, its facility premises, documents, records, electronic files, and other data or materials that the applicant or RA-HMB maintains, to enable the BCP to ensure compliance with N.J.S.A. 26:2A-17 et seq., and this chapter.

(b) Following a BCP inspection, BCP staff shall meet with representatives of the applicant or RA-HMB to perform an inspection summation, which shall describe the BCP's findings, including any deficiencies that the BCP identifies, and subsequently shall issue a written report to the applicant or RA-HMB, identifying:

1. The BCP's findings and any deficiencies that the BCP noted during the inspection;

2. If the BCP found deficiencies:

i. The date by which the applicant or RA-HMB must submit to the BCP a proposed plan of correction to cure the deficiencies; and/or

ii. If the BCP finds that the deficiencies represent an immediate threat to public health, the BCP's directed plan of correction, which will require the applicant or RA-HMB to undertake specific action to correct the deficiencies and indicate the date by which the applicant must implement the directed plan of correction.

(c) The BCP will review a proposed plan of correction that an applicant or RA-HMB submits pursuant to (b)2i above to determine whether the proposed plan would ensure compliance with N.J.S.A. 26:2A-17 et seq., and this chapter, and thereupon issue written notice to the applicant or RA-HMB:

1. Indicating whether the BCP accepts the plan of correction;

2. Directing the applicant or RA-HMB to implement the aspects of the plan that the Department accepts; and

3. If applicable:

i. Directing the applicant or RA-HMB to submit by a specified date a revised plan of correction for the parts of the plan, if any, that the BCP determines to be unacceptable; and/or

ii. Issuing a BCP-directed plan of correction, and/or taking enforcement action.

(d) An applicant or RA-HMB shall notify the BCP, in writing, upon completion of its implementation of a plan of correction, indicating the dates upon which it implements each aspect of the plan.

1. Following its receipt of a notice pursuant to (d) above, the BCP may conduct additional inspections, as necessary, to confirm the satisfactory implementation of the plan of correction.

2. Upon the BCP determining that an applicant or RA-HMB has timely and satisfactorily implemented an applicable plan of correction, the BCP will issue a written notice to the applicant or RA-HMB indicating that the BCP accepts the performance and implementation of the plan as satisfactory.

3. If the BCP determines that an applicant or RA-HMB has not timely and/or satisfactorily implemented or maintained compliance with an approved or directed plan of correction or an aspect thereof, the BCP shall issue written notice to the applicant or RA-HMB specifying the additional corrective actions needed and the dates by which the applicant or RA-HMB is to complete these actions, and may implement immediate enforcement actions, as necessary, to protect public health and ensure compliance with N.J.S.A. 26:2A-17 et seq., and this chapter, as set forth in the act at N.J.S.A. 26:2A-20 and 21 and N.J.A.C. 8:75-9.

8:75-2.5 Certificate of registration and accreditation

(a) An applicant shall not perform HMB services until the BCP issues a certificate of registration and accreditation (certificate) to the applicant.

(b) A certificate will indicate:

1. The HMB services that the BCP authorizes the applicant to perform;

2. Each other authorized location at which the BCP authorizes an RA-HMB to perform HMB services; and

3. The expiration date of the certificate, which will be for a period of no longer than 12 months from issuance.

(c) An RA-HMB shall perform only the HMB services that the BCP authorizes the RA-HMB to perform, as the RA-HMB's certificate indicates.

(d) An RA-HMB shall prominently display its certificate at a location in the RA-HMB that is readily accessible to public view and inspection in the applicant's principal place of business.

1. The BCP will issue a separate certificate to each other authorized location to which it grants registration and accreditation;

2. The certificate that the BCP issues for the other authorized location will indicate the HMB services that the Department authorizes the other authorized location to perform and the expiration date of the certificate; and

3. The other authorized location shall display its certificate at a location on its premises that is readily accessible to public view and inspection, perform only the HMB services that its certificate indicates, and otherwise comply with applicable provisions at N.J.S.A. 26:2A-17 et seq., and this chapter.

8:75-2.6 Renewal of registration and accreditation

(a) To renew a certificate, an RA-HMB shall submit either electronically through the ALIS portal or by regular mail to the BCP, at least 45 days before the expiration of its certificate:

1. The information, documentation, and fee requested pursuant to N.J.A.C. 8:75-2.2(a)1 through 4 and 2.3(a)2, if applicable, and the completed form of application at N.J.A.C. 8:75 Appendix; and

2. Documents reflecting the RA-HMB's track record that have been issued since the effective date of the RA-HMB's existing certificate, as described at N.J.A.C. 8:75-2.2 and 2.3, as applicable.

(b) Upon finding that an RA-HMB's application for renewal of its certificate is complete and the RA-HMB has paid the applicable fee, the BCP will review the application and the track record documentation that the RA-HMB submits pursuant to (a) above and

may perform an onsite inspection of the RA-HMB's premises pursuant to N.J.S.A. 26:2A-19 and N.J.A.C. 8:75-2.4.

(c) The BCP shall renew the RA-HMB's registration and accreditation if the BCP determines that:

1. The RA-HMB's application demonstrates that the premises, equipment, operational capacity, personnel (including the administrator, medical director, and medical advisory committee), and policies and procedures, have been and continue to be fit and adequate;

2. The RA-HMB's track record indicates that the applicant is operating, and there is reasonable assurance that the applicant will continue to operate, in compliance with:

i. N.J.S.A. 26:2A-17 et seq., and this chapter;

ii. Applicable Federal, State, and local government standards;

iii. Applicable accrediting body standards; and

iv. Applicable Federal, State, local government, and accrediting body-approved or directed plans of correction.

(d) If an RA-HMB timely submits an application for renewal and the applicable fee, the RA-HMB's existing registration and accreditation will not lapse pending the BCP's final determination on the application.

(e) An RA-HMB remains responsible to submit reportable events to the Department pursuant to N.J.A.C. 8:75-3.6 during the pendency of its application for renewal.

8:75-2.7 Fees; travel costs

(a) Subject to (b) below, the following are applicable fees associated with the operation of an RA-HMB:

Action	**Fee**
Initial registration and accreditation of an HMB that holds accreditation in good standing with an accrediting body, plus applicable costs pursuant to (b) below	$1,500
Initial registration and accreditation of an HMB that does not hold accreditation in good standing with an accrediting body, plus applicable costs pursuant to (b) below	$1,500

Annual renewal of registration and accreditation of an HMB that maintains accreditation in good standing with an accrediting body, plus applicable costs pursuant to (b) below	$1,500
Annual renewal of registration and accreditation of an HMB that does not hold accreditation in good standing with an accrediting body, plus applicable costs pursuant to (b) below	$1,500

(b) If an applicant or RA-HMB is located out-of-State, the applicant shall pay the travel costs that the BCP incurs to perform an onsite inspection fee, in addition to the fee at (a) above.

1. The BCP shall send the applicant an invoice for the travel costs, which the applicant shall pay within 30 days of transmittal.

2. The Department shall calculate travel costs in accordance with the New Jersey Department of the Treasury Travel Regulation (Circular No. 20-04-OMB) (September 6, 2019), as amended and supplemented, available at https://www.nj.gov/infobank/circular.

3. If the Department estimates that travel costs for a scheduled, announced inspection will exceed $1,500, the BCP shall send an invoice to the applicant or RA-HMB in advance of the inspection, specifying a deposit amount for the travel costs that the applicant or RA-HMB is to pay in advance of the inspection.

i. The BCP shall refund any unexpended funds following the conclusion of the travel.

(c) An applicant or RA-HMB shall submit applicable fees either electronically through the ALIS portal, or by regular mail or courier service to the BCP, payable to the Treasurer, State of New Jersey.

8:75-2.8 Cessation of operations; change in ownership

(a) An RA-HMB shall notify the BCP, in writing, of an intended cessation of operations or proposed transfer of ownership at least 45 days before the intended date of cessation or transfer.

(b) Registration and accreditation as an RA-HMB are not assignable or transferable and shall be immediately void if the facility ceases to operate, if the HMB's ownership changes, or if the HMB is relocated to a different site.

(c) A person proposing to own or operate an existing RA-HMB shall apply to the Department for registration and accreditation in accordance with N.J.A.C. 8:75-2.1 and shall not commence operation of the HMB until the person obtains BCP registration and accreditation following Department review of the application as if the HMB were a new facility.

1. To facilitate continuity of operations without interruption of an RA-HMB that the existing owner or operator proposes to transfer, the proposed transferee entity may apply to the BCP for registration and accreditation as the new owner or operator of the existing RA-HMB in anticipation of closing or conclusion of a proposed transfer, and the BCP will undertake best efforts to conclude its review before the anticipated closing date, provided the transferee entity submits its application for registration and accreditation at least 45 days prior to the anticipated date of the closing or conclusion of the proposed transfer of ownership or operations.

8:75-2.9 Provisional registration and accreditation

(a) The Department shall deem an existing HMB that is fully operational as of (the effective date of this chapter) to be a provisionally registered and accredited HMB (PRA-HMB) and thereby authorized to continue existing operations in the State without interruption; provided:

1. The HMB is in good standing with, as applicable, an accrediting body and/or the FDA, and fully compliant with all applicable Federal standards and approved or directed plans of correction and, if the entity operates an HMB in a jurisdiction other than the State of New Jersey, the HMB is fully compliant with all applicable Federal standards and the standards of the other jurisdiction, and approved or directed plans of correction of the Federal government or the other jurisdiction;

2. The HMB submits to the BCP written notice of its intention to apply for registration and accreditation as an RA-HMB by (30 days after the effective date of this chapter), certifying therein that it is in compliance as indicated at (a)1 above, along with

the information required in pages one and two of the application form at N.J.A.C. 8:75 Appendix; and

3. The HMB applies to the BCP for registration and accreditation pursuant to N.J.A.C. 8:75-2.1 by (60 days after the effective date of this chapter).

(b) Upon receipt of an HMB's notice of intention pursuant to (a)2 above, the BCP will issue a certificate of provisional registration and accreditation to the HMB reflecting the HMB's status as a PRA-HMB.

(c) PRA-HMB status shall remain effective until the earlier of either:

1. The BCP's issuance of a final determination on the PRA-HMB's application for registration and accreditation as an RA-HMB; or

2. The PRA-HMB's abandonment of an application for registration and accreditation pursuant to N.J.A.C. 8:75-2.1(c)3.

(d) An existing HMB as described at (a) above that performs HMB services in the State without having obtained provisional registration and accreditation in accordance with this section is subject to BCP enforcement action for violation of N.J.S.A. 26:2A-17 et seq., pursuant to N.J.S.A. 26:2A-18, 20, and 21, and this chapter.

(e) A PRA-HMB remains responsible to submit reportable events to the Department pursuant to N.J.A.C. 8:75-3.6 during the pendency of its PRA-HMB status, notwithstanding its anticipated or actual submission of an application for RA-HMB status.

SUBCHAPTER 3. ADMINISTRATION; POLICIES AND PROCEDURES

8:75-3.1 Administrator qualifications and functions

(a) An RA-HMB shall appoint a full-time administrator who has:

1. A bachelor's degree in a healthcare-related field and either:

i. A minimum of three years of work experience in maternal or pediatric healthcare, or a minimum of 10 years of work experience in a clinical healthcare setting; or

ii. A minimum of three years of work experience in the management of a food manufacturing facility.

(b) If the BCP authorizes an RA-HMB to provide HMB services at another authorized location that is within the State, the RA-HMB's administrator can serve concurrently as administrator for the other authorized location.

(c) An RA-HMB shall designate an alternate administrator who shall have the qualifications identified at (b) above to act in the administrator's absence.

(d) An administrator shall oversee and manage an RA-HMB's performance of the HMB services that the BCP authorizes the RA-HMB to provide, to ensure the RA-HMB's compliance with N.J.S.A. 26:2A-17 et seq., and this chapter.

8:75-3.2 Medical director qualifications and functions

(a) An RA-HMB shall appoint a medical director who:

1. Is a licensed physician in good standing; and

2. Has at least four years of experience in pediatrics, neonatology, or obstetrics.

(b) If an RA-HMB's administrator meets the qualifications of a medical director, the administrator may function as both the administrator and medical director.

(c) A medical director shall:

1. Maintain an RA-HMB's policies and procedures in accordance with N.J.A.C. 8:75-3.4, in consultation with the RA-HMB's medical advisory committee; and

2. Provide counsel to the administrator and the RA-HMB staff concerning medical or healthcare-related aspects of the HMB services that the BCP authorizes the RA-HMB to perform.

8:75-3.3 Medical advisory committee

(a) An RA-HMB shall appoint a medical advisory committee consisting of a minimum of three members to provide advice in the RA-HMB's development, implementation, and maintenance of the RA-HMB's policies and procedures in accordance with N.J.A.C. 8:75-3.4.

(b) A medical advisory committee shall consist of healthcare professionals with training and experience in the following fields:

1. Infectious disease;

2. Pediatrics or neonatology;

3. Lactation;

4. Obstetrics;

5. Pathology;

6. Nutrition; and/or

7. Gastroenterology.

(c) A medical advisory committee may include members who are not healthcare professionals, such as individuals with demonstrated experience in food manufacturing safety; provided:

1. Healthcare professionals comprise the majority of the members; and

2. A quorum exists only when healthcare professionals are in the majority among the members present.

8:75-3.4 Required policies and procedures

(a) An RA-HMB, in consultation with its medical director and medical advisory committee, shall establish, document in writing, implement, and review and revise, as necessary, and at least annually, policies and procedures to ensure the safety and quality of the DHM that it collects, processes, stores, and/or distributes, which are consistent with:

1. Evidence-based, peer-reviewed best practices, guidelines, and recommendations for the performance of HMB services; see, for example:

i. Arslanoglu S, Moro G, Tonetto P, et al., "Recommendations for the establishment and operation of a donor human milk bank," *Nutrition Reviews*, 81(S1) (April 2023), available at https://doi.org/10.1093/nutrit/nuad012; and

ii. PATH, "Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs" (February 2019), PATH, Seattle, WA 98109, telephone: (206) 285-3500, electronic mail address: info@path.org, available at http://www.path.org/hmb-toolkit; and

2. All applicable Federal standards, the AAP guidance, N.J.S.A. 26:2A-17 et seq., and this chapter.

(b) An RA-HMB shall make its written policies and procedures readily accessible to its staff and, upon request, the Department.

(c) An RA-HMB's policies and procedures shall address, at a minimum, the following, as applicable to the HMB services that the BCP authorizes the RA-HMB to perform:

1. Initial and periodic repeat donor screening, serological testing, and follow-up reassessment of each applicant to be a DHM donor and qualified DHM donor, in accordance with N.J.A.C. 8:75-4, including a protocol as described at N.J.A.C. 8:75-4.2(d), for determining:

i. Whether and for how long the RA-HMB must defer or exclude a qualified donor from DHM donation if the donor is consuming, receiving, or using a medication, medical device, treatment modality, immunization, or other therapy; and

ii. Whether an RA-HMB may accept, and use to perform HMB services, DHM from a donor as described at (c)1i above;

2. Donor education in accordance with N.J.A.C. 8:75-4.3;

3. Temperature, time, recordkeeping, and storage requirements for expression, storage, and transportation of DHM to which the RA-HMB is to require a DHM donor to adhere to prior to the DHM donor's relinquishment of DHM to an RA-HMB;

4. Tracking, traceability, and attendant recordkeeping of DHM from the point of expression to:

i. Distribution to a hospital or an ultimate consumer; or

ii. Disposal or other final disposition;

5. Staff training and evaluation, including implementation of ongoing informal and formal training that is relevant to each staff member's job functions to ensure competency and compliance with applicable safety and continuing quality improvement standards;

6. Pathogen testing of DHM;

7. Pasteurization of DHM;

8. Temperature and time criteria for storage of PHM, requiring, at a minimum:

i. Storage in a freezer at a temperature no higher than minus-18 degrees Celsius (0 degrees Fahrenheit); or

ii. Storage in a refrigerator at a temperature between one degree Celsius (34 degrees Fahrenheit) and four degrees Celsius (39 degrees Fahrenheit);

9. Use of equipment and instruments in accordance with manufacturer's instructions, including regular inspection and monitoring of sensors and alarms, validation, calibration, and maintenance of equipment used in handling and processing of DHM, and maintenance of records documenting these activities;

10. Establishment and dissemination of a written disclosure statement identifying the risks to an infant of consumption of PHM, which an RA-HMB is to give a parent who obtains PHM directly from an RA-HMB;

11. Establishment and dissemination of written instructions to inform a parent as to proper handling, storage, preparation, and disposal upon expiration of PHM;

12. Establishment and implementation of an emergency preparedness plan that addresses the implementation of contingency arrangements to ensure continuity of services to parents and hospitals that rely on the availability of a steady supply of DHM from the RA-HMB to address the needs of infants, such as by entering into a shared services agreement with another HMB to maintain a consistent backup supply of DHM;

13. Establishment and implementation of a process by which the RA-HMB informs recipients of PHM as to methods to submit a complaint or report a concern to the RA-HMB or the BCP; and

14. Recordkeeping.

8:75-3.5 Maintenance of records

(a) In accordance with the policies and procedures that an RA-HMB establishes pursuant to N.J.A.C. 8:75-3.4, an RA-HMB shall maintain records relating to its donors, its performance of HMB services, and recipients to whom the RA-HMB distributes PHM, including, at a minimum, the following information:

1. The donor's identification number, name, contact information, and screening and qualification file, in accordance with N.J.A.C. 8:75-4;

2. Data as to the collection of DHM, in accordance with N.J.A.C. 8:75-5;

3. Data as to the storage of DHM, in accordance with N.J.A.C. 8:75-6;

4. Data as to the processing of DHM, in accordance with N.J.A.C. 8:75-7; and

5. Data as to the distribution of DHM, in accordance with N.J.A.C. 8:75-8.

(b) Subject to (c) below, and absent the express, written consent of the subject of a record or information an RA-HMB maintains, an RA-HMB shall maintain in a confidential manner, and shall not share or disclose, records and information relating to:

1. A donor, a donor's infant, household members, and sexual partners; and

2. A DHM recipient.

(c) An RA-HMB:

1. Shall make donor and recipient records available to the Department upon request; and

2. May share donor or recipient records with another RA-HMB, as needed, by either, to comply with N.J.S.A. 26:2A-17 et seq., or this chapter.

(d) Each RA-HMB shall maintain records concerning DHM for a period of 23 years from the RA-HMB's final disposition of the DHM.

8:75-3.6 Reportable events

(a) An RA-HMB shall notify the BCP within 24 hours (and preferably immediately), by telephone, followed by written notice within two business days, through the ALIS portal, by regular mail, or by electronic mail, upon its discovery of:

1. An adverse reaction, outcome, or illness realized by a consumer of DHM that is suspected or confirmed to be attributable to the consumer's consumption of DHM from the RA-HMB;

2. A recall of DHM by the RA-HMB or another entity with regulatory authority over the RA-HMB;

3. An error or accident that occurs in the RA-HMB's performance of HMB services that could negatively impact the purity, safety, and quality of DHM;

4. The occurrence of an event that impacts the premises or operational continuity of the RA-HMB, such as fire, flood, earthquake, outbreak of illness, HVAC failure, or utility outage; and

5. The failure of any equipment that is critical in processing DHM.

i. The notice of failure shall identify the specific equipment involved, the duration of the failure, the actions the RA-HMB is undertaking to remediate the failure, and, if applicable, the batch or lot numbers of affected DHM.

(b) An RA-HMB shall issue written notice to the BCP, through the ALIS portal, by regular mail, or by electronic mail, within five business days of:

1. The discontinuation of the employment of the RA-HMB's administrator, alternate administrator, or medical director, and shall identify therein the person who will serve in an acting or a permanent status in place of the discontinued employee, in accordance with (b)2 below;

2. The RA-HMB's appointment, whether in an acting or permanent status, of an administrator, alternate administrator, or medical director.

i. The notice shall provide the appointee's name, telephone number, electronic mail address; and

ii. The educational and experiential credentials that an RA-HMB submits regarding an appointee to the position that the BCP requires an RA-HMB to submit, upon application for issuance or renewal of registration and accreditation as an RA-HMB, at pages 3, 4, and 5 of the application form at N.J.A.C. 8:75 Appendix.

8:75-3.7 Responsibility for delegated services.

(a) An RA-HMB that delegates to a third party, the performance of an element of an HMB service that the BCP authorizes the RA-HMB to perform:

1. Remains responsible for the third party's performance of the delegated HMB service; and

2. Is subject to enforcement proceedings for any noncompliance with N.J.S.A. 26:2A-17 et seq., and this chapter by the third party.

(b) For example, if an RA-HMB retains a refrigerated trucking service to transport DHM, and a refrigeration failure occurs during transport, the distributing RA-HMB is subject to Department enforcement action pursuant to N.J.S.A. 26:2A-17 et seq., and this chapter for the refrigeration failure, and, if applicable, consequences resulting therefrom.

SUBCHAPTER 4. DONOR SELECTION AND TRAINING

8:75-4.1 Donor identification, screening, and qualification

(a) An RA-HMB shall assign a unique donor identification number to each person who applies to the RA-HMB to be a DHM donor.

(b) In accordance with policies and procedures it establishes pursuant to N.J.A.C. 8:75-3.4, an RA-HMB shall initially screen, in writing and through a spoken interview, and reassess at least every three months thereafter, and more frequently as needed, each donor for health and lifestyle conditions and behaviors that may:

1. Affect the quality, safety, and nutritional value of DHM the donor provides;

2. Impair the health of the donor or, if applicable, the donor's infant; or

3. Conflict with the donor's right and ability to exercise self-determination.

(c) An RA-HMB, at a minimum, in accordance with (b) above, shall screen each donor for the following:

1. A contraindication that the applicable Federal standards identify, especially the CDC breastfeeding guidance referred to at N.J.A.C. 8:75-1.3(d);

2. Physical, emotional, or behavioral health conditions;

3. Language barriers or other communication impediments that may impede the donor's ability to provide informed consent, and understand and consistently adhere to the RA-HMB's donor education and policies and procedures for the sanitary expression, collection, storage, transmittal, and/or transportation of DHM;

4. Dietary restrictions or nutritional deficiencies;

5. Use of any contraindicated substances as determined by the medical director and informed by LactMed®;

6. Chronic or acute infection or illness;

7. Contraindicated prescribed medications;

8. Breastfeeding history and duration, including, if applicable, the age of the donor's infant;

9. Behavioral and lifestyle history of the donor and the donor's recent sexual partners, that places either at elevated risk for human immunodeficiency virus (HIV) infection, or other infectious disease, including, but not limited to:

i. Receipt of tattoos, piercings, or permanent makeup;

ii. Receipt of an organ or tissue transplant or blood transfusion; or

iii. Incarceration, accidental needle stick, or injection drug use;

10. Environmental exposure to heavy metals, such as lead and mercury;

11. Travel to, and time spent living outside of the United States, including on United States military bases overseas, at any time in the donor's life; and

12. Any infectious or communicable diseases or other medical conditions affecting the health of members of the donor's household.

(d) An RA-HMB shall require a prospective donor to supply a written statement from the donor's healthcare professional and, if applicable, the healthcare professional of the donor's infant, which identifies:

1. Risks to the donor and, if applicable, the donor's infant, attendant to the donor's participation in DHM donation;

2. The general health status of the donor, and, if applicable, the donor's infant;

3. Whether the healthcare professional has determined that the donor's donation of DHM is contraindicated;

4. Medications, vitamins, and/or supplements that are prescribed for the donor; and

5. If applicable, whether the volume of milk the donor produces exceeds the amount that is sufficient to appropriately nourish the donor's infant, and whether limitations or qualifications apply to this assessment.

(e) An RA-HMB shall require each prospective donor, no earlier than three months prior to the donor's first milk donation and every three months thereafter, to undergo serological testing for HIV, human T-lymphotropic virus (HTLV), hepatitis B, hepatitis C, and syphilis.

1. The RA-HMB shall ensure that the donor's serological testing results indicate that the serological testing was conducted no earlier than three months before the donor's first DHM donation.

(f) If the result of any serological testing for the conditions listed at (e) above is reactive, positive, or indeterminate, the RA-HMB shall exclude the prospective donor from donating DHM.

(g) In accordance with its policies and procedures and the CDC donor guidance at N.J.A.C. 8:75-1.3(d), and following its review of a prospective donor's written screening, spoken interview, and serological testing, and the statements of the healthcare professional of the donor and, if applicable, the donor's infant, an RA-HMB shall defer or exclude a prospective donor from donating DHM, either temporarily until a disqualifying factor no longer exists, or permanently:

i. In accordance with the criteria at N.J.A.C. 8:75-4.2; and/or

ii. If the acceptance of the donor's DHM could be harmful to the donor, the donor's infant, and/or a recipient of the donor's DHM.

(h) An RA-HMB that collects DHM directly from a donor shall obtain the donor's written and signed informed consent to:

1. The performance of HMB services using the donor's DHM; and

2. The RA-HMB's retention of records relating to the health of the donor and the donor's infant, household, and sexual partners.

(i) An RA-HMB shall require each prospective and qualified donor to report immediately to the RA-HMB a change to:

1. The health of the donor, or the donor's infant or household members;

2. The medications the donor takes; and

3. A fact or circumstance that would affect the accuracy or completeness of the donor's responses to the RA-HMB's written screening questionnaire or spoken interview questions.

(j) An RA-HMB, in accordance with N.J.A.C. 8:75-4.2 and the RA-HMB's policies and procedures, shall:

1. Review a change that a donor reports pursuant to (i) above;

2. Implement appropriate responsive action, which may include repeat serological testing; and

3. If indicated, temporarily defer or permanently exclude the donor from further donation of DHM.

(k) An RA-HMB shall retain the documentation of its donor screening, donor's informed consent, and the written statements of the healthcare providers of the donor and, if

applicable, the donor's infant, that it obtains pursuant to this chapter in the donor's record on file with the RA-HMB.

8:75-4.2 Donor exclusion and deferral criteria

(a) An RA-HMB shall exclude from donating DHM a person who:

1. Has a health condition or lifestyle practice that contraindicates acceptance of DHM from the proposed donor, pursuant to the CDC breastfeeding guidance at N.J.A.C. 8:75-1.3(c);

2. Has been incarcerated, or has a sexual partner who has been incarcerated, for more than three consecutive days in the preceding three months;

3. Has had, or has a sexual partner who has had, an accidental needle stick in the preceding three months, and, after undergoing serological testing for the diseases listed at N.J.A.C. 8:75-4.1(e) at least three months after the needle stick, obtains a positive result on any test;

4. Has a current or past infection relevant to breastfeeding, such as HIV-1, HIV-2, HTLV-1, HTLV-2, hepatitis B, hepatitis C, or syphilis;

5. Has had, or has a sexual partner who has had, in the preceding three months, an ear or body-piercing, a tattoo, or a permanent makeup application, with other than a single-use instrument, with a nonsterile needle, or from an unregulated site or establishment that is not in compliance with N.J.A.C. 8:27, Body Art and Ear-Piercing Facility Standards, and, after undergoing serological testing for all of the diseases listed at N.J.A.C. 8:75-4.1(c), at least three months after the piercing, tattoo, or permanent makeup application, obtains a positive result on any test;

6. Regularly consumes more than one standard alcoholic drink per day, as specified in the CDC Breastfeeding Special Circumstances Guidance at N.J.A.C. 8:75-1.3(d), in the subtopic on "Alcohol";

7. Has engaged in injection drug use or has a sexual partner who has engaged in injection drug use, within the preceding 12 months;

8. Currently uses any contraindicated substances, as determined by the medical director and informed by LactMed®;

9. Is a vegetarian or vegan and does not take vitamin B12 supplements;

10. Has a history of leukemia or lymphoma;

11. Has received chemotherapy or radiation treatment in the preceding three years;

12. Has or had a blood relative who has been diagnosed with Creutzfeldt-Jakob Disease (CJD), any variant thereof, or transmissible spongiform encephalopathy, or is at risk of any of the foregoing diseases due to any of the following:

i. Spent five or more years in total in France or Ireland at any time from the beginning of 1980 to the end of 2001;

ii. Received a blood transfusion in the United Kingdom, France, or Ireland at any time from the beginning of 1980 through present;

iii. Spent three months or more in the United Kingdom at any time from 1980 through 1996; or

iv. Has received a dura mater transplant;

13. Uses any tobacco or nicotine-containing products, cigars, or cigarillos, in any form, including gum, patches, or electronic cigarettes;

14. Has received, or has a sexual partner who has hemophilia or who has received, a blood transfusion or blood products, except RhoGAM, in the preceding three months, and, after undergoing serological testing in accordance with N.J.A.C. 8:75-4.1(e) performed at least three months after the blood transfusion or receipt of the blood product, obtains a positive result on any test;

15. Has received, or has a sexual partner who has received, an organ or tissue transplant in the preceding three months, and, after undergoing serological testing in accordance with N.J.A.C. 8:75-4.1(e) performed at least three months after the transplant, obtains a positive result on any test; or

16. Has been exposed to the Ebola virus within the preceding 28 days and has become ill as a result.

(b) Nothing in this chapter shall be construed to limit the ability of an RA-HMB to establish policies for exclusion and deferral that are more stringent than those in this section.

(c) An RA-HMB shall not accept DHM, and shall defer a donor from donating DHM if, within the eight days preceding the donor’s expression and proposed donation of DHM,

the donor or the donor's sexual partner receives a piercing, tattoo, or permanent makeup application from a regulated establishment using a sterile needle and single-use-only dye.

1. The RA-HMB shall defer the donor for eight days following the piercing, tattoo, or application, and, if the recipient of the piercing, tattoo, or permanent makeup application does not have symptoms of skin infection at the conclusion of the eighth day, any DHM expressed by the donor during those eight days may be donated and the RA-HMB may use the DHM in its performance of HMB services.

(d) In evaluating the eligibility of a prospective or qualified donor and the health and safety risk to an ultimate consumer a donor's DHM, an RA-HMB shall apply the protocol it establishes pursuant to N.J.A.C. 8:75-3.4(a)1 to determine:

1. Whether, and for how long, an RA-HMB must defer or exclude a qualified donor from DHM donation if the donor is consuming, receiving, or using a medication, medical device, treatment modality, therapy, or immunization as described at in this subsection; and

2. Whether an RA-HMB may accept, and use to perform, HMB services, and DHM from a donor as described at (a)1 above.

(e) An RA-HMB's medical director, in consultation with the RA-HMB's medical advisory committee, shall develop the protocol that an RA-HMB is to establish pursuant to (d) above, based on research and information from the CDC, the FDA, the pharmaceutical and human milk-banking industry, and taking into consideration, among other factors they deem relevant:

1. The molecular weight, half-life, transmissibility through breast milk, and lipid solubility, of each substance the donor consumes, receives, or uses; and

2. The weight of a typical ultimate consumer of DHM.

(f) An RA-HMB's medical director, in consultation with the RA-HMB's medical advisory committee, shall review and update the protocol it establishes pursuant to (d) above, as necessary, to reflect evolving best practices, and at least annually.

8:75-4.3 Donor education program

(a) An RA-HMB shall implement a donor education program, the curriculum of which is consistent with N.J.S.A. 26:2A-17 et seq., this chapter, any applicable Federal standards, the AAP guidance, and its policies and procedures.

(b) An RA-HMB shall administer its donor education program to the donor in the donor's language and ensure that each donor completes and comprehends the donor education program before donating DHM to the RA-HMB.

(c) The donor education program shall address, at a minimum, the following topics:

1. The purpose of an RA-HMB and the intended ultimate consumers of DHM;

2. Donor responsibilities;

3. The RA-HMB's policies and procedures, as applicable to a donor, specifically concerning safety protocols for DHM;

4. Sanitary expression, collection, storage, and transmittal or transportation of DHM, including:

i. Maintaining personal hygiene in connection with expression of DHM;

ii. If applicable, using and maintaining a breast pump, in accordance with manufacturer instructions, including sanitization;

iii. Handwashing;

iv. Safely using and handling containers that the RA-HMB supplies to a donor to collect and store DHM; and

v. Using proper procedures for refrigeration, freezing, storage, and transmittal or transportation of DHM to an RA-HMB, as applicable, including time and temperature monitoring and documentation, and the prohibition against heating DHM;

5. Donor obligations with respect to labeling DHM containers, such as recording the date of expression;

6. Medical conditions, diseases, and use of medications or other substances by a donor and/or members of a donor's household that a donor is to disclose to an RA-HMB;

7. Diet and nutrition recommendations;

8. The effects of smoking and/or ingesting any substance that is contraindicated for DHM, as informed by LactMed; and

9. Guidance to assist donors in avoiding and responding to common lactation difficulties and health problems, and resources that are available to assist donors.

SUBCHAPTER 5. COLLECTION OF DHM

8:75-5.1 Collection of DHM

(a) In collecting DHM, an RA-HMB that the Department authorizes to collect DHM shall adhere to N.J.S.A. 26:2A-17 et seq., this chapter, any applicable Federal standards, the AAP guidance, and its policies and procedures.

(b) An RA-HMB shall collect DHM only from a qualified donor or another RA-HMB.

(c) An RA-HMB shall:

1. Obtain the informed consent of each donor prior to the collection of DHM;

2. Supply pre-sterilized, leak-proof containers and container seals to each donor, on which the RA-HMB has affixed a tag or label on which the donor is to specify the date of expression and providing:

i. The donor’s RA-HMB identification number; and

ii. A space wherein the RA-HMB is to indicate the date and time of collection from the donor.

(d) An RA-HMB shall not use to perform HMB services, DHM that was heated or improperly stored before collection.

(e) An RA-HMB shall maintain records as to the means by which the RA-HMB collects DHM from a donor, such as by drop off, pickup, or through a courier delivery service.

SUBCHAPTER 6. STORAGE OF DHM

8:75-6.1 Storage of DHM

(a) In storing DHM, an RA-HMB that the Department authorizes to store DHM shall adhere to N.J.S.A. 26:2A-17 et seq., this chapter, any applicable Federal standards, the AAP guidance, and its policies and procedures.

(b) An RA-HMB shall store DHM using refrigeration or freezing equipment that the RA-HMB exclusively dedicates to the storage of DHM and adhere to the AAP Storage Recommendations at N.J.A.C. 8:75-1.4(a)4i.

SUBCHAPTER 7. PROCESSING DHM

8:75-7.1 Processing DHM

(a) In processing DHM, an RA-HMB that the Department authorizes to process DHM shall adhere to N.J.S.A. 26:2A-17 et seq., this chapter, any applicable Federal standards, the AAP guidance, and its policies and procedures.

(b) In processing DHM, an RA-HMB shall record:

1. The dates of pasteurization and other processing activities;

2. The composition of the batch by donor identification number; and

3. The results of all pathogen testing performed.

SUBCHAPTER 8. DISTRIBUTION OF DHM

8:75-8.1 Distribution of DHM

(a) In distributing DHM, an RA-HMB that the Department authorizes to store DHM shall adhere to N.J.S.A. 26:2A-17 et seq., this chapter, any applicable Federal standards, the AAP guidance, and its policies and procedures.

(b) An RA-HMB that distributes DHM directly to a parent shall provide a written statement of the risks of an infant’s consumption of DHM to that parent in the parent’s language, and shall undertake reasonable efforts to ensure that the parent comprehends the notice.

1. If a language other than English is the prevailing language spoken by at least 10 percent of the RA-HMB’s service area, the RA-HMB shall make available and provide to a parent, as appropriate, the written notice translated into that language, and in English.

(c) In distributing DHM, an RA-HMB shall record:

1. The date of distribution;

2. The method of distribution, such as transportation by vehicle, use of a courier service, and/or by mail;

3. The intended recipient and/or ultimate consumer;

4. The date dispensed, the batch or lot identifiers for the dispensed PHM;

5. If an RA-HMB dispenses PHM directly to a parent, the name, address, and telephone number of the parent, the name, address, and date of birth of the infant who is the ultimate consumer, a copy of the prescription order, and a copy of the written acknowledgment of the risks of an infant's consumption of DHM that the RA-HMB issues to the parent pursuant to (b) above, and which the parent has signed; and

6. If an RA-HMB dispenses to a hospital, the hospital name, address, and telephone number.

SUBCHAPTER 9. ENFORCEMENT ACTIONS AND HEARINGS

8:75-9.1 Enforcement actions

(a) The Department may summarily suspend the registration and accreditation of an RA-HMB when the continued registration and accreditation of the RA-HMB poses an immediate or serious threat to public health, safety, or welfare.

1. An RA-HMB whose registration and accreditation the Department summarily suspends shall have the right to apply for an expedited hearing, as provided at N.J.A.C. 8:75-9.2.

2. A summary suspension shall take effect immediately upon issuance.

(b) The Department may suspend or revoke an RA-HMB's accreditation and registration, issue to the RA-HMB, a formal written warning, and/or refuse to issue or renew the RA-HMB's registration and accreditation, for violation(s) of any portion of N.J.S.A. 26:2A-17 et seq., or this chapter, including:

1. Demonstrated inability to provide HMB services in a consistently safe manner;

2. Deceptive or fraudulent procurement of registration and accreditation, or renewal thereof;

3. Conducting an HMB service that the Department did not authorize the RA-HMB to provide;

4. Unauthorized disclosure of confidential donor or recipient information;

5. Willful preparation of false or fraudulent records, or the inducement of others to do so;

6. Destruction of records that N.J.S.A. 26:2A-17 et seq., and this chapter require an RA-HMB to maintain;

7. Willful obstruction of any inspection or investigation by the Department; or

8. Any other action that poses a threat to public health, safety, or welfare.

(c) In accordance with N.J.S.A. 26:2A-21, the Department may impose monetary penalties against an RA-HMB that:

1. Uses fraud or misrepresentation in obtaining registration and accreditation as an RA-HMB, or in renewal thereof; or

2. Violates any provision of N.J.S.A. 26:2A-17 et seq., and this chapter.

(d) In accordance with N.J.S.A. 26:2A-21, a monetary penalty for:

1. A first offense is no less than $100.00 and no more than $1,000; and

2. A second or any subsequent offenses is no less than $500.00 and no more than $5,000.

(e) For a monetary penalty, each violation is a single, separate occurrence on each calendar day the violation occurs or remains uncorrected.

(f) If an RA-HMB is longer than 60 calendar days in arrears on the payment of a monetary penalty, the Department may:

1. Refuse to renew the registration and accreditation of the RA-HMB;

2. Institute a summary civil proceeding pursuant to the Penalty Enforcement Law, N.J.S.A. 2A:58-1 et seq.; and/or

3. Take other action authorized by law.

8:75-9.2 Hearings

(a) If the Department summarily suspends the registration and accreditation of an RA-HMB, then the RA-HMB may request an expedited hearing by submitting a request to the Department, in writing, within 30 days of the date of the summary suspension notice.

1. The request shall contain a response to the charges contained in the summary suspension notice; and

2. Failure to submit a request for a hearing within 30 days of the date of the summary suspension notice shall render the summary suspension a final agency decision.

(b) A summary suspension shall remain in effect unless the Department lifts or rescinds it through a final agency decision or other decision or Department action.

(c) Nothing in this chapter shall be construed to prevent the Department from concurrently or thereafter moving to suspend or revoke the RA-HMB's accreditation and registration, issuing a directed plan of correction, and/or imposing a monetary penalty.

(d) If the Department proposes to issue a monetary penalty, and/or to suspend, revoke, or refuse to issue or renew a registration and accreditation, the Department shall afford the HMB applicant or RA-HMB an opportunity for a hearing to contest the proposed action.

1. A monetary penalty assessment, suspension (excluding a summary suspension), or revocation of the registration and accreditation of an HMB applicant or RA-HMB, shall become effective 30 calendar days after the date of the notice of the proposed action.

i. If the affected HMB applicant or RA-HMB wishes to contest the action, within such 30-day period, then it shall submit a written notice requesting a hearing to the Department, to the attention of the Office of Legal and Regulatory Compliance, NJ Department of Health, PO Box 360, Trenton, NJ 08652-0360. The penalty, suspension (excluding a summary suspension), or revocation shall be held in abeyance until the hearing has been concluded and a final decision has been rendered.

ii. Failure to submit such written notice shall result in the HMB applicant or RA-HMB forfeiting all rights to such a hearing.

2. If an HMB applicant or RA-HMB wishes to contest the Department's refusal to issue or renew a registration and accreditation, the applicant or RA-HMB shall submit, within 30 days of the date of the refusal, a written request for a hearing on the matter to the Department at the address at (d)1i above.

i. Upon the submission of a written notice requesting a hearing to contest the refusal to renew the accreditation and registration of an RA-HMB, the refusal

shall be held in abeyance until the hearing has been concluded and a final decision is rendered.

ii. A refusal to issue a registration and accreditation is effective immediately.

iii. Failure to submit a written request for a hearing to contest a refusal to issue or renew an RA-HMB shall result in the HMB applicant or RA-HMB forfeiting all rights to such a hearing.

(e) All hearings shall be conducted in accordance with the New Jersey Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the New Jersey Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(f) All enforcement actions shall be posted on the Department's website at https://www.nj.gov/health/phel/clinical-lab-imp-services/enforcement_actions.

8:75-9.3 Enforcement against operation without Department registration and accreditation

(a) In accordance with N.J.S.A. 26:2A-18, a person shall not operate an HMB or perform an HMB service in the State of New Jersey without first obtaining a registration and accreditation from the BCP.

(b) Upon notice or discovery that a person is operating an HMB or providing an HMB service within the State of New Jersey without first obtaining registration and accreditation from the BCP, the Department may issue an order directing that person or entity to immediately cease and desist the performance of HMB services.

1. Failure to comply with an order to cease and desist may result in an action by the Department for injunctive relief in the Superior Court of New Jersey, in accordance with N.J.S.A. 26:2A-20.

2. The Department shall post orders to cease and desist on the Department's website as a public notice.

(c) In addition to the issuance of an order to cease and desist, the Department may:

1. Impose a monetary penalty in accordance with N.J.S.A. 26:2A-21 when a person is found to have operated an HMB or provided HMB services without first obtaining registration and accreditation from the BCP; and/or

2. Refuse to issue the person a HMB registration and accreditation.

New Jersey Department of Health
Clinical Laboratory Improvement Services
Biobanking Compliance Program

INSTRUCTIONS FOR COMPLETION OF

APPLICATION FOR REGISTRATION AND ACCREDITATION OF A HUMAN MILK BANK

Following are instructions for completion of an application for registration and accreditation of a human milk bank (HMB), pursuant to N.J.S.A. 26:2A-17, et seq., and N.J.A.C. 8:75.

The application form must be completed in full and returned with requested attachment and the appropriate fee. Fees are non-refundable and incomplete applications will not be processed.

Checks or money orders should be made payable to the ***"Treasurer, State of NJ"*** and include the human milk bank code (if available). You may also make your payment using the electronic payment link on the Clinical Laboratory Improvement Services website (https://www.nj.gov/health/phel/clinical-lab-imp-services/). Please include a copy of the Department of Health Payment Confirmation with the application.

The completed application for registration and accreditation and all requested attachments should be mailed to:

Regular Mail (US Postal Service)

Biobanking Compliance Program

PHEL/Clinical Laboratory Improvement Services

New Jersey Department of Health

PO Box 361

Trenton, NJ 08625-0361

Overnight Delivery (FedEx, UPS)

Biobanking Compliance Program

PHEL/Clinical Laboratory Improvement Services

Public Health, Environmental and Agricultural Laboratory

New Jersey Department of Health

3 Schwarzkopf Drive

Ewing, NJ 08628-1620

REGISTRATION AND ACCREDITATION

An applicant for initial, or renewal of, registration and accreditation to operate an HMB must complete this form, attach all requested documentation, and submit the application, and the requisite fee, to the appropriate address above.

Upon approving an application, the Department will issue a Certificate of Registration and Accreditation that indicates the HMB services that the Department authorizes the Registered and Accredited Human Milk Bank (RA-HMB) to perform.

Registration and Accreditation is not transferable.

New Jersey Department of Health
Clinical Laboratory Improvement Services
Biobanking Compliance Program

APPLICATION FOR REGISTRATION AND ACCREDITATION OF A HUMAN MILK BANK

FOR NJDOH USE ONLY			
Date Mailed	Date Received	☐ Approved ☐ Other:	Denied
Received By	Check Number	Amount	Check Date

APPLICATION
Type of Application (check all that apply): ☐ Initial Registration and Accreditation by Deemed Status (HMBANA-accredited entity) ☐ Initial Registration and Accreditation ☐ Renewal of Registration and Accreditation by Deemed Status (HMBANA-accredited entity) Provide existing RA-HMB Code: ☐ Renewal of Registration and Accreditation Provide existing RA-HMB Code: ☐ Provisional Registration and Accreditation

HMB AND OPERATOR 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	Name and Address of Registered Agent for Service of Process or other entity authorized to receive official notices on behalf of the HMB
Telephone Number of HMB	Telephone Number of Owner or Operator
HMB Email Address	Owner or Operator Email Address
Website	

Which of the following HMB services is the applicant seeking authorization to perform (check all that apply)?

☐ Collection ☐ Processing ☐ Storage ☐ Marketing ☐ Distribution

OWNERSHIP AND ORGANIZATIONAL STRUCTURE

Check all that apply:

☐ For Profit ☐ Not for Profit

Attach Business Registration Certificate

☐ Individual or Sole Proprietorship

☐ If doing business or trading under another name, state the name:

☐ Partnership: Attach sheet listing names, addresses, and telephone numbers of each partner, and respective ownership share of each

☐ LLC: Attach sheet listing names, addresses, and telephone numbers of each member, and respective ownership share of each

☐ Corporation: State of Incorporation:

Attach copy of Articles of Incorporation

☐ Government Agency: Indicate type: ☐ State ☐ County ☐ Municipality

☐ Other:

List name, address, telephone number of any other HMB that is owned or operated by the applicant or a parent or subsidiary of the applicant in any jurisdiction:

HMB Name	Telephone Number
Address	Email Address
Website	

HMB Name	Telephone Number
Address	Email Address:
Website	

HMB ADMINISTRATOR

Name of HMB Administrator	Telephone Number
Email Address	

Attach the resume or curriculum vitae of the HMB Administrator

Does the Administrator serve as the **Administrator** for another HMB in any jurisdiction? ☐ Yes ☐ No						
If yes, provide the names and addresses of other milk banks at which the Administrator serves as the Administrator. Attach additional sheets as necessary.						
HMB Name						
Address						
Website						
Indicate specific hours spent each day at this location (e.g., 9 am to 5 pm):						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
HMB Name						
Address						
Website						
Indicate specific hours spent each day at this location (e.g., 9 am to 5 pm):						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Does the Administrator serve as the **Medical Director** for another HMB in any jurisdiction? ☐ Yes ☐ No						
If yes, provide the names and addresses of other milk banks at which the Administrator serves as the Medical Director. Attach additional sheets as necessary.						
HMB Name						
Address						
Website						
Indicate specific hours spent each day at this location (e.g., 9 am to 5 pm):						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

DESIGNATED ALTERNATE HMB ADMINISTRATOR		
Name of Alternate HMB Administrator	Telephone Number	
Email Address		
Attach the resume or curriculum vitae of the Designated Alternate HMB Administrator		
HMB MEDICAL DIRECTOR		
Name of HMB Medical Director	Telephone Number	
Email Address		
Medical License Number	Issuing State	Date Issued
Medical License Number	Issuing State	Date Issued
Medical License Number	Issuing State	Date Issued
Attach the resume or curriculum vitae of the Medical Director		
Does the Medical Director currently serve as **Medical Director** for another milk bank in any jurisdiction? ☐ Yes ☐ No *If yes, provide the names and addresses of other milk banks at which the Medical Director currently serves as Medical Director. Attach additional sheets as necessary.*		
HMB Name		
Address		
Website		
HMB Name		
Address		
Website		

HMB MEDICAL ADVISORY COMMITTEE			
List each member of the applicant's Medical Advisory Committee and attach each member's resume or curriculum vitae. Attach additional sheets as necessary.			
Name		Telephone Number	
Address			
Health Care professional credential	License or certification number	Issuing State	Date Issued
Name		Telephone Number	
Address			
Health Care professional credential	License or certification number	Issuing State	Date Issued
Name		Telephone Number	
Address			
Health Care professional credential	License or certification number	Issuing State	Date Issued
Name		Telephone Number	
Address			
Health Care professional credential	License or certification number	Issuing State	Date Issued
Name		Telephone Number	
Address			
Health Care professional credential	License or certification number	Issuing State	Date Issued

OTHER AUTHORIZED LOCATION	
If applicant is seeking authorization to perform an HMB service in the State of New Jersey other than at its primary place of business, list each other authorized location. **NOTE:** A separate application must be submitted for each other authorized location	
Business Name	HMB service performed
Address	Primary contact name and telephone number

ACCREDITING ORGANIZATION MEMBERSHIP	
Is the applicant or RA-HMB a member of the Human Milk Bank Association of North America (HMBANA)	
☐ Yes ☐ No If yes, attach a copy of the HMBANA certificate of accreditation with current seal	
I, the undersigned, certify that the statements made herein are true and accurate. I am aware that if any of the statements made herein are willfully false, I am subject to punishment.	
Signature of HMB Owner or Operator	Date

Required Document Checklist (please attach copies of requested documents; original documents will not be returned):

ALL APPLICATIONS (Initial and Renewal):

- ☐ Certificate of Incorporation or Articles of Formation, if applicable
- ☐ Business Registration Certificate, if applicable
- ☐ Resume or Curriculum Vitae of Administrator reflecting required education and experience, and diploma
- ☐ Resume or Curriculum Vitae of Designated Alternate Administrator reflecting required education and experience, and diploma
- ☐ Resume or Curriculum Vitae of Medical Director, and proof of current licensure
- ☐ Lease or deed for premises
- ☐ Certificate of occupancy, if applicable
- ☐ Requisite Fee: Check or money order payable to "Treasurer, State of NJ," or electronic payment at https://www.nj.gov/health/phel/clinical-lab-imp-services (if electronic payment, please attach copy of the Department of Health Payment Confirmation with this application)

INITIAL REGISTRATION AND ACCREDITATION:

☐ All applicants:

- Reports of the last inspections that the FDA, the State of New Jersey, a county, or a municipality, as applicable, performed at the premises that is the subject of this application (including, for each, any deficiencies found, any approved or directed plan of correction (POC), and report on status of compliance with any POC)

☐ Track Record Review:

- With respect to each other HMB that the applicant, or a subsidiary or parent of the applicant, owns or operates in New Jersey or in another jurisdiction, If applicable:
    - The report of the last inspection that HMBANA, the FDA, the State of New Jersey, the county, the municipality, and/or the other jurisdiction performed (including any deficiencies found, approved or directed POC, and report on status of compliance with POC)

☐ HMBANA-accredited applicants:

- Certificate of Accreditation by HMBANA with seal
- Report of the most recent inspection that HMBANA performed at the premises that is the subject of this application (including any deficiencies found, any approved or directed POC, and report on status of compliance with any POC)

RENEWAL OF REGISTRATION AND ACCREDITATION

☐ RA-HMB Track Record information and documentation issued since the effective date of RA-HMB's existing Certificate of Registration and Accreditation

Number of additional pages attached: