Filed April 23, 2026

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

BIOBANKING COMPLIANCE PROGRAM

Human Milk Bank Registration and Accreditation

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

Proposed: April 21, 2025, at 57 N.J.R. 796(a).

Adopted: January 29, 2026, by Dr. Raynard E. Washington, Acting Commissioner, Department of Health.

Filed: April 21, 2026, as R.2026 d.072, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

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

Effective Date: May 18, 2026.

Expiration Date: May 18, 2033.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received comments from the following:

1. Alyson C. Fuller, PhD, JD, Vice President, Government Affairs and Intellectual Property, Prolacta® Bioscience, Duarte, CA;

2. Rachel Granger, Executive Director, The New York Milk Bank, Valhalla, NY;

3. Lindsay Groff, Executive Director, Human Milk Banking Association of North America (HMBANA), Fort Worth, TX;

4. Kathryn McLaughlin and Mary Lou Moramarco, Advocacy Committee Co-Chairs, New Jersey Breastfeeding Coalition, Manasquan, NJ;

5. Denise O'Connor, Executive Director, Mid-Atlantic Mothers' Milk Bank, Pittsburgh, PA; and

6. Deborah C. Youngblood, PhD, Chief Executive Officer, Mothers' Milk Bank Northeast, Newton Upper Falls, MA.

The numbers in parentheses following each comment below, correspond to the commenter numbers listed above.

General Support

1. COMMENT: A commenter appreciates "the Department's publication of the [proposed new] rules [at] N.J.A.C. 8:75 … When paired with the reimbursement provided elsewhere in the law, the proposed [new rules] will enable greater access to this vital nutrition." (1)

2. COMMENT: A commenter "appreciate[s] the time the … Department … has dedicated to researching and developing the proposed [new rules, is] grateful for the … [Department's] commitment to supporting human milk banking[,] and look[s] forward to continuing to work with hospitals and families across the State." (2)

3. COMMENT: A commenter is "encouraged to see the Department prioritizing safe, regulated access to donor milk[,] appreciate[s] the Department's efforts to support families and NICU providers[,] and share[s] the goal of building a robust and safe donor milk system in New Jersey." (3)

4. COMMENT: A commenter "commend[s] the Department's efforts to ensure safe, ethical, and equitable access to donor human milk across New Jersey. The implementation of

[the proposed new] rules represents an important step toward enforcing [the Act], which mandates insurance coverage of donor human milk for medically fragile infants," and states that the "proposed [new] rules are comprehensive and well researched, appropriately reflecting the complexity of milk bank operations." (4)

5. COMMENT: A commenter states that the proposed new rules are "well[-]researched[,] comprehensive, [and take] into account nearly every aspect of milk banking[. The commenter] recognize[s] that this is a large undertaking given the unique nature of … milk bank operations [and thanks the Department] for [its] work to ensure that babies have what they need to thrive …" (5)

6. COMMENT: A commenter "appreciate[s] all the research and knowledge of public health principles that are evident in [the proposed new] rules. Milk banks are new territory for some state health departments, and it makes sense that one wants to ensure the utmost safety in [their] practices." (6)

RESPONSE TO COMMENTS 1 THROUGH 6: The Department acknowledges the commenters' support of the Department's efforts.

Federal Standards

7. COMMENT: A commenter "has serious concerns with the Department's characterization of the current state of [F]ederal regulation as well as the Department's endorsement of 'Deemed' status to accredit [HMBANA] members[. T]he current proposal amounts to an abdication of the responsibility delegated to the Department by the Legislature and an endorsement of human milk banking standards that the Department, by its own acknowledgement, has not read in full and therefore cannot fully understand. Rather than

providing certainty as to the safety of [DHM] products … this could create a false sense of security for parents and providers.

The Department, in its Federal Standards Statement, concedes that the [FDA] 'does not presently regulate DHM from HMBANA-accredited HMBs as a 'food' under its jurisdiction … the FDA's standards for infant formula and exempt infant formula would not apply to HMBANA-accredited facilities[, and] the Department does not have full access to HMBANA['s] HMB standards.' [(Citation omitted.)] Nonetheless, the Department declares that 'HMBANA's accrediting standards and processes appear to track the FDA standards applicable to infant formula and exempt infant formula manufacturing and distribution establishments.' [(Citation omitted.)] The Department's basis for making this assertion rel[ies] on HMBANA's assurances that the organization 'maintains a comprehensive system of preventative controls,' etc. [(Citation omitted.)]

The Department's acceptance of these claims at face value fly in the face of common sense and best practice in food safety. The fact that the FDA does not regulate HMBANA milk banks is not *prima facie* evidence of the safety of donor human milk provided by HMBANA-affiliated entities, but rather an alarming gap in [F]ederal food safety standards. This gap led in no small part to the Legislature's interest in this issue in the first place and has also been criticized repeatedly by Congress in recent years, including in the 2023 Omnibus appropriations bill [to which] the Department cites.

For its part, the FDA has stressed that HMBANA's guidelines are just that, guidelines, and that the FDA has not vetted them ('FDA has not been involved in establishing these voluntary guidelines or state standards'). [(Citation omitted.)] In fact, no independent organization has certified the HMBANA guidelines' equivalency with FDA or any other food

safety standards. The Department proposes to continue this state of affairs by not conducting a full review of the guidelines, which[,] as the Department notes in its Federal Standards Statement[,] are not public and are available for purchase only by HMBANA members, an issue in and of itself.

[T]he intent of the 2017 law was to establish a safe, stable supply of donor human milk that would be accessible to all eligible infants in New Jersey. By providing reimbursement, the [S]tate would further health equity, and by insisting on registration and meeting minimum standards, the [S]tate would ensure the safety of these vulnerable infants. The … proposed [new] rule does not provide a sufficient level of oversight for milk banks and does not adequately protect the human milk supply, as required by the 2017 law.

Luckily, there are alternatives. As the Department rightly notes in its Federal Standards Statement, the FDA does maintain standards on infant formula manufacturers, including exempt infant formula manufacturers like Prolacta. Although the FDA does not actively enforce these standards on HMBANA milk banks or on other producers of donor human milk, the Department could choose to incorporate the infant formula standards by reference. 21 CFR [Parts] 106 and 107 include a number of relevant provisions that could be applied to donor human milk banks, including current good manufacturing practice (GMP) requirements, production and in-process controls, labeling requirements and recall provisions that exceed those applicable to normal foods under the Food Safety Modernization Act (FSMA) and other provisions of [F]ederal law.

These requirements are generally not prescriptive but give regulators flexibility to interrogate processes in formula manufacturing environments and require improvements, as necessary. While applying these principles to [HMBs] may appear unconventional, they much

more closely mirror legislative intent. The Legislature hoped that the Department would take an active role in ensuring the safety of [DHM]. By deferring this responsibility, and particularly without having thoroughly vetted the standards of the organization to which the Department is deferring its responsibility, the Department is violating the spirit of the 2017 law." (1)

RESPONSE: The Department disagrees with the commenter's statement that through the proposed new rules, the Department would abdicate its oversight responsibility. The Department would review each RA-HMB application individually and on its own merits. Pursuant to proposed new N.J.A.C. 8:75-2.3, the Department would determine to register and accredit an applicant that is an HMBANA-accredited entity only if the applicant demonstrates the ability to operate in compliance with the Act, proposed new N.J.A.C. 8:75, and applicable Federal, State, and local government standards, accrediting body standards, and plans of correction. Upon review of an RA-HMB application, the Department would have the opportunity to review each applicant's policies and procedures for consistency with the Federal standards, regulatory guidance documents, and AAP guidance that proposed new N.J.A.C. 8:75-1.3 and 1.4 would incorporate by reference. The Department may conduct an onsite inspection of an applicant's facility in accordance with N.J.S.A. 26:2A-19 and proposed new N.J.A.C. 8:75-2.4, and, as part of that inspection, must have access to review "documents, records, files, or other data" that the applicant maintains, and the premises and operations.

Proposed new N.J.A.C. 8:75-1.3(b) would incorporate by reference the provisions of Title 21 of the Code of Federal Regulations (CFR) that the commenter identifies. Should the FDA promulgate regulations applicable to DHM and HMBs, in compliance with the mandate established within the Consolidated Appropriations Act of 2023 or another Federal law, those

regulations likely would be codified within Title 21 of the CFR, and thereby become applicable to an RA-HMB upon their effective date, pursuant to N.J.A.C. 8:75-1.3(b).

Based on the foregoing, the Department will make no change upon adoption in response to the comment.

8. COMMENT: A commenter states that "[r]ecognizing HMBANA accreditation as part of the [S]tate's oversight framework could help avoid duplicative inspections and fees, since accredited milk banks already meet stringent safety standards and undergo external review." (3)

9. COMMENT: A commenter "emphasize[s] the importance of *safe, ethical, and barrier-free access* to donor human milk, especially for vulnerable infants. This aligns with *Strategy 2.6 of the New Jersey Breastfeeding Strategic Plan*: 'Identify and address obstacles to greater availability of pasteurized human donor milk for infants who need it, especially fragile infants.'" The commenter "urge[s] that this guiding principle remain central as [the proposed new rules] are finalized." The commenter states that "HMBANA is the *recognized gold standard* for nonprofit milk banking in the [United States of America], with: *Uncompensated donors* (avoiding ethical and safety risks)[;] *Unmanipulated milk*, preserving its natural properties[; and] *Pasteurization using the Holder Method* (62.5 [degrees Centigrade] for 30 minutes), which ensures safety while retaining key immunological benefits. Given HMBANA's rigorous accreditation and auditing process," the commenter "*recommend[s] that accreditation be deemed sufficient to meet [State] regulatory requirements*, or that a modified auditing/inspection process be allowed for accredited milk banks, as is the case in other states. [(Emphasis in original.)]" (4)

10. COMMENT: A commenter states that the “vast majority of health systems across the United States [of America] rely on the network of nonprofit milk banks for their donor milk needs. HMBANA standards are widely recognized as the ‘gold standard’ of safe and ethical milk banking and have yielded a decades[-]long, exceptional safety record with accredited milk banks serving the sickest infants in the nation. The guidelines are kept up to date with current medical evidence and maintaining accreditation involves a vigorous auditing and inspection process.

The expertise and standards of HMBANA are focused solely on the nonprofit milk banking model[,] which includes three important features:

[1.] *An uncompensated donor model:* HMBANA accredited milk banks are strictly prohibited from remunerating donors due to the introduction of safety and ethical considerations for both the donor and the donor’s baby.

[2.] *Milk is unmanipulated:* HMBANA does not allow milk banks to add anything to milk or manipulate milk in a way that would differ from naturally occurring maternal milk.

[3.] *Pasteurization:* [Pursuant to] FDA, [S]tate, and HMBANA guidelines, donor milk must undergo a bioburden[-]reduction process. HMBANA requires donated milk to be pasteurized only and specifically using the Holder Method (62.5 [degrees Centigrade] for 30 minutes). This method inactivates a broad range of pathogens while retaining a significant portion of key components such as secretory [immunoglobulin A]. Donor milk is more than nutrition. High heat processes to create shelf stable milk have been shown to destroy important bioactive properties and virtually nothing is known about the clinical implications. Of note, nearly all research on donor milk and the prevention of necrotizing enterocolitis and other

NICU complications has been done using donor milk processed by the Holder Method or other similar pasteurization protocol.

Given the robustness of HMBANA accreditation, [the commenter] *request[s] consideration of allowing current HMBANA accreditation to be deemed rigorous and sufficient for meeting the operational requirements of regulation. This approach has been taken by several other states and was included in earlier versions of the law to mandate insurance coverage of donor milk in New Jersey*. Alternatively, the inspection and auditing provisions could be modified for HMBANA[-]accredited milk banks. Both approaches would greatly reduce costs and [D]epartment administrative burden. [(Emphasis in original.)]" (5)

11. COMMENT: A commenter states that "*nonprofit accredited milk banks have been safely operating for many years under the expert standards of HMBANA and [its] highly credentialed medical board.* [The commenter] *urge*[s the Department] *to:*

1) Meet with HMBANA leadership and [its] *standards committee to better understand* [its] *national safety and compliance standards and auditing processes[;]*

2) Consider aligning [the proposed new rules] *to match … HMBANA*['s standards] *for nonprofit milk banks that do not compensate donors*[, which] *are already accepted by hospitals across the country*[; and]

3) Create a more streamlined approach for oversight of nonprofit HMBANA[-]*accredited milk banks recognizing the effective safety measures and oversight already in place.* [(Emphasis in original.)]

Nonprofit milk banks operate to ensure that safe donor milk is available to all the babies who need it. [They] have limited resources, and [their] work is hindered when [they] have to manage milk supplies and administrative requirements differently based on individual state

standards. [The commenter] want[s] to be sure that [the proposed] new [rules] do not inadvertently limit the milk that is available to New Jersey families by setting standards that are not aligned with the rest of the country. If milk banks have to segregate milk supplies because of outlier [rules] for New Jersey, [they] will be less able to support the demand from New Jersey hospitals and families." (6)

RESPONSE TO COMMENTS 8, 9, 10, AND 11: The Department refers commenters to proposed new N.J.A.C. 8:75-2.3, which would recognize HMBANA as an accrediting body and identify procedures by which an accredited applicant could apply for registration and accreditation by deemed status. N.J.S.A. 26:2A-19 obliges the Department to conduct an onsite inspection of each registered and accredited milk bank at least once every five years, irrespective of a milk bank's accreditation status. Proposed new N.J.A.C. 8:75-1.3, 1.4, and 2.3 establish standards with which an applicant for RA-HMB status must demonstrate the ability to comply as a condition of Department registration and accreditation, and renewal thereof.

HMBANA accreditation is only available to nonprofit human milk banks. The proposed new rules would establish standards intended to ensure that a donor does not donate milk at the expense of the health of the donor or the donor's newborn, and that each potential donor is screened for health and lifestyle conditions, and factors that might impair a donor's right and ability to exercise self-determination, regardless of whether the donor would receive compensation. Therefore, the Department will make no change upon adoption in response to the comments.

Subchapter 2. Issuance and Renewal of Registration and Accreditation; Inspection; Fees

N.J.A.C. 8:75-2.1 Application for Registration and Accreditation; Authorized HMB Services

12. COMMENT: With respect to proposed new N.J.A.C. 8:75-2.1(b)2i, a commenter states that "[a]s part of [their] activities, many HMBANA[-]accredited milk banks have milk depots and milk dispensaries. Milk depots are monitored donation drop off locations for previously approved milk donors. These locations have gone through a screening and selection process and are also monitored regularly for adherence to HMBANA standards by the respective milk bank. Similarly, milk dispensaries are locations that distribute milk to outpatients. These locations have also been vetted and are monitored regularly for adherence to HMBANA standards by each respective milk bank. Both the milk depots and milk dispensaries operate on a voluntary basis and are important elements of supporting community access. A concern with requiring these locations to go through the same scope of registration requirements is that … very few organizations [would be] willing to participate in New Jersey given the cost and paperwork involved. To provide perspective … 28 milk depots in New York State … provide vital access to donor milk. [T]o develop a similar network in New Jersey, the registration fees alone would be cost[-]prohibitive and a significant deterrent. Therefore … the [Department should] eliminate the extensive registration process and fee schedule for these operations and instead allow them to be considered part of the original entity's operations. As part of the original entity, they could remain subject to inspection and the milk bank would be required to regularly update the [Department] on changes in management, name and/or address for each location." (2)

13. COMMENT: A commenter states, “[r]equiring depots and dispensaries to register as independent HMBs is excessive. These facilities are community partners, often uncompensated. [The Department should r]equire milk banks to list these sites and notify the Department of additions[, and o]utline basic freezer and documentation requirements without full accreditation.” (4)

14. COMMENT: A commenter states that proposed new N.J.A.C. 8:75-2.1(b)2i “implies that each depot and dispensary would need the full panoply of regulation creating an undue burden for the department, milk banks, and the hosts. Depots are facilities (typically hospitals, practices, health centers, and other organizations that are involved in maternal child health) that host a freezer to collect milk from approved local donors. Dispensaries are hosts that have a small amount of processed milk to distribute for low volume immediate use such as bridge milk. A nonprofit milk bank’s network of depots and dispensaries plays an important role in maintaining an ample donor milk supply and is a vital link to the local community. Many states have dozens of depots. The hosts of depots and dispensaries are voluntarily providing this service to their community. The hosts are not paid by the milk bank and absorb the costs of maintaining the depot or dispensary. The costs and burden created by the proposed requirements could deter facilities from providing this needed service and may make depots not viable for nonprofit milk banks that collect and distribute milk in New Jersey. HMBANA guidelines already address the safe operations of depots and dispensaries for nonprofit milk banks.” The commenter “suggests that milk banks must list depots and dispensaries in their applications and notify the [D]epartment when new locations are added. Further defining the scope of these sites and elaborating on the basic requirements of depots and dispensaries

(freezers that maintain temperatures of 18 [degrees Centigrade], documentation in accordance with the procedures of the milk bank) could be considered." (5)

RESPONSE TO COMMENTS 12, 13, AND 14: Proposed new N.J.A.C. 8:75-1.2 would define the term "human milk bank" by reference to the Act at N.J.S.A. 26:2A-17, which defines the term "human milk bank" and lists the services that an HMB might perform, for which it must obtain Department registration and accreditation pursuant to N.J.S.A. 26:2A-18. These services include "collection" and "storage" of human milk, which are services that the entities the commenters describe as "depots" perform. The Department is without discretion to refrain from either requiring an entity that performs HMB services from obtaining registration and accreditation or subjecting the entity to periodic onsite inspection.

Notwithstanding the status of these facilities as charitable hosts, the Department would nonetheless incur costs to register, accredit, inspect, and otherwise oversee these entities. However, to alleviate the financial burden of registration and accreditation on facilities that exclusively collect frozen human milk from donors and store it until the transfer to another facility for processing, that is, "depots," the Department will make a change upon adoption to the fee schedule at proposed new N.J.A.C. 8:75-2.7 to establish a new fee category for the initial and renewal of registration and accreditation of such entities at the reduced amount of $500.00. Based on the commenters' representations, it appears that an RA-HMB that is a depot would not perform the required tasks associated with donor identification, screening, selection, and education, and that the RA-HMB that is the processing facility to which a depot would transfer the DHM it collects would perform this function. Thus, a depot's functions would be limited to recording information about each donation and the collection method, pursuant to

proposed new N.J.A.C. 8:75-5.1, and ensuring that the DHM was and remains appropriately stored, pursuant to proposed new N.J.A.C. 8:75-6.1.

The Department will make no corresponding change with respect to the facilities the commenters refer to as “dispensaries,” because these entities would perform, in addition to receipt and storage of human milk, the additional HMB service of “distribution,” pursuant to proposed new N.J.A.C. 8:75-8. Distribution would involve confirming that the parent to whom a dispensary distributes processed DHM acknowledges the risks associated with an infant’s consumption of DHM and has the requisite prescription order, and complying with associated recordkeeping obligations, and, thereby, would require more substantial Department oversight.

Except as described above, the Department will make no change upon adoption in response to the comments.

N.J.A.C. 8:75-2.5 Certificate of Registration and Accreditation

15. COMMENT: With respect to N.J.A.C. 8:75-2.5(b)3, a commenter states that the Department should consider a two-year period of validity of a certificate of registration “to reduce the paperwork requirements,” and states that this change would “align with New York State’s current issuance of a [two]-year license.” (2)

RESPONSE: The Department is without discretion to establish a period of registration longer than one year. N.J.S.A. 26:2A-18 requires the Department to conduct a “yearly assessment” of each HMB and assess an “annual registration fee.” Therefore, the Department will make no change upon adoption in response to this comment.

N.J.A.C. 8:75-2.7 Fees; Travel Costs

16. COMMENT: With respect to proposed new N.J.A.C. 8:75-2.7, a commenter states that "[t]he proposed accreditation and annual renewal fees are very high and would pose a challenge to nonprofit human milk banks. Nonprofit milk banks operate on very lean budgets." The commenter inquires whether the Department would "consider a one-time registration fee and no renewal fee," and states that an HMB registered in New York State does not pay any fees for registration.

The commenter further states that "being required to cover the cost of inspection fees is out of the ordinary." The commenter states that the resources of "a nonprofit organization" providing HMB services "are limited and budgeted on an annual basis. It would be challenging to bear the cost of an inspection, particularly if it were not anticipated in the budget." The commenter states that the New York State Department of Health and the FDA cover "the costs associated with their travel and expenses" to perform onsite inspections. The commenter requests that the Department consider "waiving these fees for HMBANA[-]accredited organizations." (2)

17. COMMENT: With respect to proposed new N.J.A.C. 8:75-2.7, a commenter states that the proposed fees "are the highest nationally" and that "HMBANA-accredited banks already undergo extensive audits." The commenter recommends that the Department "[w]aive or reduce fees for accredited nonprofit banks and eliminate the requirement for routine onsite inspection unless concerns arise." (4)

18. COMMENT: With respect to proposed new N.J.A.C. 8:75-2.7, a commenter states that the proposed fees "are the highest in the country and are quite significant for nonprofit milk banks. Non-profit milk banking is a critical, but under[-]resourced medical service in the

healthcare delivery system, often relying on financial contributions and community support. HMBANA[-]accredited milk banks are regularly audited and inspected with vigorous standards which have been deemed sufficient by [the Department], greatly decreasing the burden of scrutiny. The audit of a nonaccredited milk bank would need to be much more rigorous." The commenter requests that the Department consider assessing "a lower fee on nonprofit milk banks accredited by HMBANA" and "lift the requirement for onsite inspection for HMBANA[-]accredited milk banks and instead have accredited milk banks subject to inspection as [the Department deems] necessary." (5)

19. COMMENT: A commenter "recommend[s] additional research into the need for substantial commitment of [Department] resources to provide accreditation and license milk banks that are already nationally accredited by HMBANA. This is redundant and creates more administrative burdens on small nonprofits as well as [the Department]. [The] proposed licensing fees are higher than … in any of [the] other 11 states [in which the commenter operates] and likely the highest in the country." The commenter states that a "nonprofit milk bank is providing a service to New Jersey families, [and] should not be required to pay [the Department's] accreditation-related travel and services, especially [if a facility has] safety measures in place that have supported New Jersey effectively and safely for many years." The commenter "suggest[s that the Department] remove the onsite inspection requirement for HMBANA milk banks as this is effectively performed by [the] national accreditor[, and] consider a two-tiered system that has more limited auditing and licensing fees for [HMBANA-accredited] nonprofit milk banks … than for those that are operating independently and require significant review and oversight." (6)

RESPONSE TO COMMENTS 16, 17, 18, AND 19: N.J.S.A. 26:2A-18 requires the Department to offset its costs of administering the program of HMB registration, accreditation, and oversight through the assessment of corresponding annual HMB registration and accreditation fees. N.J.S.A. 26:2A-19 requires the Department to conduct an onsite inspection of each RA-HMB at least once every five years. Therefore, the Department is without discretion to waive fees for initial and renewal of registration and accreditation or decline to perform an onsite inspection at least once every five years, in addition to an initial licensure and/or periodic or complaint-based inspection that it might perform. Travel costs payable by an RA-HMB located out-of-State would be infrequent, and presumptively reasonable in that they would be calculated, pursuant to proposed new N.J.A.C. 8:75-2.7(b)2, in accordance with the travel regulation of the New Jersey Department of the Treasury. The Department has no basis upon which to evaluate the commenter's assertion that nonprofit milk banks that are not HMBANA-accredited necessarily will "require significant review and oversight" as compared to HMBANA-accredited HMBs.

As stated above in response to previous comments, the Department is making a change upon adoption to establish a reduced fee category for depots.

Notwithstanding the Department's obligation pursuant to N.J.S.A. 26:2A-18 to offset its operational costs through the establishment of registration, accreditation, and inspection fees, the fees at proposed new N.J.A.C. 8:75-2.7 would likely be insufficient to recoup even 10 percent of the Department's anticipated initial and ongoing costs to establish and operate a program for the registration, accreditation, and oversight of HMBs. The fees at proposed new N.J.A.C. 8:75-2.7 would reflect the Department's inability to project the number of entities that will apply for registration and accreditation in the first year of the program, and its reluctance to

deter the availability of RA-HMB services in the State by imposing the bulk of Department's HMB oversight program startup costs, in addition to its ongoing operational expenses, on the first set of applicants, in the hope of being able to amortize its recovery of these costs over time. The Department anticipates promulgating a future rulemaking to adjust its fees in subsequent years to reflect the Department's development of additional data as to its costs to administer the program, and based on factors, such as the annual number of applicants, their geographic distribution, and the anticipated establishment and implementation of Federal regulation and oversight of HMBs to support or reduce the Department's oversight burden. However, the Department does not wish, from the outset, to hinder or impede either the ability of HMBs to initiate or maintain operations in the State or the availability of PHM to those in need of it. To address the commenters' concerns, the Department will make a change upon adoption to lower the fees for initial and renewal of registration and accreditation for HMBs that hold accreditation in good standing with an accrediting body and for HMBs that do not hold accreditation in good standing with an accrediting body to $1,000.

Except as described above, the Department will make no change upon adoption in response to the comments.

Subchapter 3. Administration; Policies and Procedures

N.J.A.C. 8:75-3.1 Administrator Qualifications and Functions

20. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.1, a commenter states that the "qualifications outlined for an administrator would limit the potential candidate pool for the role and do not accurately reflect the current leadership of nonprofit human milk banks. While milk banks have the singular focus of working with one product, the running and

management of an organization would benefit from many different experience backgrounds including individuals with MBAs or MPHs. Additionally, the clinical healthcare experience as well as maternal or pediatric care are areas of expertise typically covered by the Medical Director and the Medical Advisory Committee." The commenter recommends that the Department not adopt N.J.A.C. 8:75-3.1(a). (2)

21. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.1, a commenter states that "[t]he proposed requirements limit eligible candidates and do not reflect current nonprofit leadership models ..." and recommends "removing overly restrictive qualifications[.] Organizational management experience (e.g., MBA, MPH) should suffice, especially when clinical expertise is provided by the Medical Director and Advisory Committee." (4)

22. COMMENT: A commenter states that proposed new N.J.A.C. 8:75-3.1 would establish standards that "are very narrow and not aligned with the range of highly successful and regulatory compliant milk bank directors throughout the HMBANA network." The commenter states "that clinical oversight is well[-]provided by medical directors, who do not need to be the administrative director (and indeed this separation of duties may provide … important checks and balance[s]). [W]hile human milk is absolutely a food, the single entity of human milk and single process of pasteurization do not require an extensive food facility background to safely oversee. [M]ilk bank directors need to bring other types of experience in nonprofit management and decisions about who is qualified to successfully lead a nonprofit milk bank should be left to the Board of Directors for nonprofits." The commenter "recommend[s that the Department] drop this requirement." (6)

RESPONSE TO COMMENTS 20, 21, AND 22: The Department does not intend proposed new N.J.A.C. 8:75-3.1 to impose administrator credential requirements that would

result in an HMB being unable to locate appropriately qualified applicants for the position of administrator. The rule seeks to ensure that the role of HMB administrator is filled by an individual with sufficient education and transferable work experience, commensurate with the significant responsibilities of the role. To accommodate individuals with alternative work experience or education who may be appropriate to serve in the role of an administrator, the Department would entertain the granting of waivers of these qualifications in accordance with the procedure at proposed new N.J.A.C. 8:75-1.5. As the Department's oversight of RA-HMBs develops, the Department will continue to evaluate the credentials needed for an administrator with a view toward the development of rulemaking to revise the minimum required credentials, as appropriate, to ensure health and safety.

8:75-3.2 Medical Director Qualifications

23. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.2, a commenter states that "the proposed requirement that a medical director be licensed specifically in New Jersey could create barriers for out-of-[S]tate milk banks currently supplying hospitals in the region. Given the limited number of nonprofit milk banks nationally, this could unintentionally restrict access to donor milk for New Jersey families." (3)

RESPONSE: Proposed new N.J.A.C. 8:75-3.2(a)1 would not require the medical director of an RA-HMB to be "licensed specifically in New Jersey." However, the proposed definition of the term "healthcare professional" at N.J.A.C. 8:75-1.2 would mean a person who holds a license as a physician, an advanced practice nurse, or a physician assistant pursuant to Title 45 of the Revised Statutes of New Jersey. The Department agrees that it would be impracticable and potentially restrict New Jerseyans' access to DHM to require a person

serving an HMB as a healthcare professional licensed by another state to obtain New Jersey licensure. Therefore, in response to the comment, to alleviate this burden, and for the reasons stated by the commenter, the Department will make a change upon adoption to the definition of "healthcare professional" at N.J.A.C. 8:75-1.2 to state that a "healthcare professional" includes a person who is eligible for licensure by reciprocity as a physician pursuant to N.J.A.C. 8:35-13.35-3.2, certification by endorsement as an advanced practice nurse pursuant to N.J.A.C. 13:37-7.6, or eligible for licensure as a physician assistant pursuant to N.J.A.C. 13:35-2B.5. Thus, a person serving an HMB as a healthcare professional need not hold a New Jersey license or certification, provided the person would be eligible for New Jersey licensure or certification, as applicable, in accordance with the educational and experiential standards of the State Board of Medical Examiners or the New Jersey Board of Nursing.

8:75-3.3 Medical Advisory Committee

24. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.3, a commenter states that "[f]or milk banks that are accredited by HMBANA, [the Department] might allow a combination of the HMBANA medical and standards committee membership and the milk bank's own medical advisory committee to adhere to all of these clinical specialties. [T]he medical board of HMBANA and the HMBANA Standards Committee [set] the national guidelines that [HMBANA-accredited HMBs] follow so [HMBANA-accredited HMBs] need the key expertise at that national level and it can place an undue burden on smaller milk banks to have to replicate that." (6)

RESPONSE: Proposed new N.J.A.C. 8:75 would apply to entities that are not HMBANA-accredited and that would not have access to the HMBANA resources to which the commenter refers, such as for-profit HMBs, which are not eligible for membership in HMBANA.

Accordingly, proposed new N.J.A.C. 8:75-3.3 would require each RA-HMB to ensure that it has access to a medical advisory committee, the members of which have the indicated training and experience. Therefore, the Department will make no change upon adoption in response to this comment.

8:75-3.4 Required Policies and Procedures

25. COMMENT: A commenter notes that proposed new N.J.A.C. 8:75-3.4(c)11 would require "including instructions on how to safely discard human milk that has expired." The commenter states that "[h]uman milk that is frozen poses no threat and indeed it doesn't so much 'expire,' as become less nutritionally optimal. No special discard instructions are necessary." (6)

RESPONSE: Proposed new N.J.A.C. 8:75-3.4(c)11 would require the policies and procedures of an RA-HMB to address the "[e]stablishment and dissemination of written instructions to a parent as to proper handling, storage, preparation, and disposal upon expiration of PHM." The rule is intended to require an RA-HMB's instructions to inform a parent as to the need to dispose of spoiled or "expired" PHM, to ensure that a parent does not feed improperly handled PHM to an infant. To address the commenter's concern and to ensure that the intended meaning of the paragraph is understood, the Department will make a change upon adoption, restating paragraph (c)11 to indicate that the instructions are to address the need to dispose of, and to not feed an infant, improperly handled or otherwise spoiled PHM.

26. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.4(c)12, a commenter states that "[w]hile [the HMB that the commenter represents] do[es] not have shared service[s]

agreements with other milk banks, [the HMB that the commenter represents] maintain[s] ongoing dialogues [to] support each other in the event of an emergency." The commenter inquires whether an HMB that the commenter might "call upon" would "be required to be registered in New Jersey, or would consideration be given to waiving registration requirements in the event of an emergency? Limiting to just those milk banks registered in New Jersey could limit the accessibility of human milk in the event of an emergency." The commenter requests that the Department "include a registration waiver during emergency situations." (2)

27. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.4(c)12, a commenter states that the "[e]mergency [s]haring [r]estrictions [r]equiring NJ licensure for milk[-]sharing partnerships is unnecessarily restrictive." The commenter recommends that the proposed new rules "[a]llow collaboration with any HMBANA-accredited milk bank, as Pennsylvania does, to avoid administrative burden and service delays." (4)

28. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.4(c)12, a commenter states that "[t]here are no specific service agreements between HMBANA[-]accredited milk banks. Typically, milk banks reach out to the next closest milk banks if they need milk but can collaborate and receive/give assistance to any other HMBANA milk bank." This commenter inquires whether "RA-HMBs [would] be limited to collaboration only with other milk banks that hold a New Jersey license" and states that "this has been problematic in New York and is the primary reason why [the] milk bank [that the commenter represents] maintains a New York license. Pennsylvania allows a milk bank licensed in the Commonwealth to share or receive milk from any other HMBANA[-]accredited milk bank, even if the other milk bank does not hold a Pennsylvania license." (5)

RESPONSE TO COMMENTS 26, 27, AND 28: Proposed new N.J.A.C. 8:75-3.4(c)12 would require an HMB to have an emergency preparedness plan to ensure continuity of services to parents and hospitals that rely on the availability of DHM from the RA-HMB, "*such as* by entering into a shared services agreement with another HMB to maintain a consistent backup supply of DHM [(emphasis added)]." Thus, proposed new N.J.A.C. 8:75-3.4 would not dictate the content of an RA-HMB's emergency preparedness plan; it suggests entry into a shared services agreement (SSA) with another HMB as an example of measure that an RA-HMB might take in establishing its emergency preparedness plan. Thus, proposed new N.J.A.C. 8:75-3.4(c)12 would not require an RA-HMB to enter into an SSA with an HMB, and if an RA-HMB were to enter into an SSA with another HMB, it would not require that HMB to be an RA-HMB. However, if an RA-HMB were to elect to enter into an SSA with an HMB as part of its emergency preparedness plan, then, pursuant to proposed new N.J.A.C. 8:75-3.7, Responsibility for delegated services, the RA-HMB would remain responsible for assessing the qualifications of the other HMB and ensuring that HMB would meet the standards at N.J.A.C. 8:75. Therefore, the Department will make no change upon adoption in response to the comments.

29. COMMENT: With respect to proposed N.J.A.C. 8:75-3.4(c)13, commenters inquire whether the BCP will provide standard language that HMBs are to use to inform recipients of PHM as to methods to submit a complaint or report a concern to an RA-HMB or the BCP. The commenters state that proposed new N.J.A.C. 8:75-3.4(c)13 would "apply mostly to outpatient recipients as hospitals manage inpatient distribution" and would "only apply to outpatients for a milk bank because only the hospitals interface with inpatient recipients." (4 and 5)

RESPONSE: Proposed new N.J.A.C. 8:75 would apply to any entity that provides HMB services, which would include a hospital that collects, stores, or distributes DHM or PHM. The BCP will not provide standard language to be used by an RA-HMB to comply with proposed new N.J.A.C. 8:75-3.4(c)13. Proposed new N.J.A.C. 8:75-1.2 would identify the BCP's contact information, which an RA-HMB could use in establishing and implementing a process by which it would inform recipients of PHM as to how to communicate with the BCP. Therefore, the Department will make no change upon adoption in response to the comment.

8:75-3.6 Reportable Events

30. COMMENT: A commenter states that proposed new N.J.A.C. 8:75-3.6(a)5 "would benefit from clarifying details about what qualifies as a reportable event otherwise it is unclear what types of equipment failures notices are required." The commenter recommends, "limiting this to significant equipment failures defined by length of time or impact on operations." (2)

31. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.6(a)5, a commenter states that "[o]nly failures that significantly impact processed milk that will be distributed or the safe operations of the milk bank should be required" and that the Department should "[c]larify the scope." (4)

32. COMMENT: With respect to proposed new N.J.A.C. 8:75-3.6(a)5, a commenter states that "[c]larification of what qualifies as reportable failures needs to be made. Only failures for a significant duration [that] impact processed milk that will be distributed or the safe operations of the milk bank should be required." (5)

33. COMMENT: A commenter states that "[t]he extent of reportable events listed in [proposed new N.J.A.C. 8:75-3.6(a)1 through 5] is beyond the scope of what is relevant or reasonable for milk banks to communicate to a state entity. [The commenter's] current

standards require that [the commenter] report, within 24 hours, any distributed milk that has since been identified as out[-]of[-]compliance and therefore results in either a voluntary or required recall. [The commenter] suggests that New Jersey [align] with that requirement and [specify] that in addition to notifying the impacted recipients of the recalled milk, [an RA-HMB] also report the incident to the [D]epartment, when the incident involves New Jersey recipients." (6)

RESPONSE TO COMMENTS 30, 31, 32, AND 33: The Department notes that the reportable events listed at proposed new N.J.A.C. 8:75-3.6(a)1 through 5 would ensure that PHM distributed to recipients in the State is safe, and an RA-HMB reports an event that has the potential to negatively impact the purity, safety, and qualify of the DHM. Proposed new N.J.A.C. 8:75-3.5(a)5, which would require a facility to alert the Department in the event of a critical equipment failure, would enable the Department to prepare for and respond to a potential shortage in the availability of PHM that is needed for the critically fragile infants who are eligible to receive PHM. Therefore, the Department will make no change upon adoption in response to the comments.

Subchapter 4. Donor Selection and Training

N.J.A.C. 8:75-4.1 Donor Identification, Screening, and Selection; and 4.2 Donor Exclusion and Deferral Criteria

34. COMMENT: With respect to proposed N.J.A.C. 8:75-4.1(c)2, a commenter states that the screening process of "a HMBANA[-]accredited milk bank … focuses on factors that would affect the safety of the milk being donated. Emotional and behavioral health conditions currently fall outside the scope of those screening requirements" and requests the Department "remov[e] this as a requirement." (2)

35. COMMENT: With respect to proposed N.J.A.C. 8:75-4.1(c)2, a commenter states that “[s]creening for emotional or behavioral conditions is intrusive and not aligned with milk safety concerns.” The commenter recommends that the Department “[r]emove this requirement.” (4)

36. COMMENT: With respect to proposed N.J.A.C. 8:75-4.1(c)2, a commenter states that “[d]onor screening is confined to factors that affect the safety of donor milk for medically fragile babies including medical conditions, risk factors for exposures to blood borne pathogens, and medication/supplementation use. Emotional and behavioral health conditions are outside of this scope and are overly intrusive.” (5)

37. COMMENT: With respect to proposed N.J.A.C. 8:75-4.1(c)2, a commenter states that “[p]rospective milk donor screening should be narrowly focused on indicators that the donated milk could be unsafe for consumption. Therefore, HMBANA standards focus on medication contraindication and lifestyle choices that are risky to a safe milk supply. Questions beyond that about specific mental health diagnoses, for example, are outside of the necessary scope of this work and thus, overly intrusive. Additionally, [the commenter is] concerned about working outside of our areas of expertise, asking questions about issues that [the commenter is] not equipped to address internally.” (6)

RESPONSE TO COMMENTS 34, 35, 36, AND 37: Proposed new N.J.A.C. 8:75-4.1(b) would require an RA-HMB, in accordance with its policies and procedures, to screen each donor for factors that could affect the quality, safety, and nutritional value of DHM the donor provides; impair the health of the donor or, if applicable, the donor’s infant; or conflict with the donor’s right and ability to exercise self-determination. In performing this screening, proposed new N.J.A.C. 8:75-4.1(c)2 would require an RA-HMB, in determining whether to accept DHM

from a particular donor, to take into consideration physical, emotional, or behavioral health conditions that could affect: (1) a proposed donor's capacity or ability to adhere consistently to procedures or requirements that ensure the quality, safety, and nutritional value of the donor's milk; (2) the propriety of accepting the donor's milk given the effect of the donation on the health of the donor or the donor's infant; or (3) the donor's ability to provide informed consent to the donation, free from coercion or cognitive impairment. In addition, a discussion of these conditions could lead to a discussion of treatments and medications the donor is receiving or has received that could affect the donor's milk.

The evaluation at proposed new N.J.A.C. 8:75-4.1(c) would require an RA-HMB to confirm that a donor, for example: (1) is not under financial pressure to donate to an RA-HMB that compensates donors, to the detriment of the consumption needs of the donor's own infant; (2) comprehends the critical importance of honesty in the disclosure of underlying health conditions; and/or (3) has the intellectual capability and willingness to comply with basic handling and storage procedures. For the foregoing reasons, the Department will make no change upon adoption in response to the comments.

38. COMMENT: With respect to N.J.A.C. 8:75-4.1(c)5 and 4.2(a)8, a commenter "recommends the inclusion of *Hale's Medications and Mother's* [sic] *Milk* as a reference resource." (2)

39. COMMENT: With respect to N.J.A.C. 8:75-4.1(c)5 and 4.2(a)8, a commenter recommends that the Department "[a]dd Hales [sic] Medications [and] Mothers' Milk and the InfantRisk Center alongside LactMed[®] as approved resources." (4)

40. COMMENT: With respect to N.J.A.C. 8:75-4.1(c)5 and 4.2(a)8, a commenter recommends "including the reference document *Hale's Medications and Mother's* [sic] *Milk*, which is routinely used as a trusted source of information[, at] https://www.halesmeds.com[.]" (6)

RESPONSE TO COMMENTS 38, 39, AND 40: The National Institute of Child Health and Human Development (NICHHD), of the National Institutes of Health (NIH) of the United States Department of Health and Human Services, issues the *Drugs and Lactation Database*, commonly known as LactMed®. The NIH's National Library of Medicine (NLM) *Fact Sheet* on this publication states that "LactMed[®] is a database of drugs and other chemicals to which breastfeeding [persons] may be exposed. It includes information on the levels of such substances in [human] milk and infant blood, and the possible adverse effects in the nursing infant. Suggested therapeutic alternatives to those drugs are provided, where appropriate. All data are derived from scientific literature and fully referenced. Data are organized into substance-specific records, which provide a summary of the pertinent reported information and include links to other NLM databases. Supplemental links to breastfeeding resources from credible organizations are also provided. LactMed[®] is accessible, free of charge via the [NLM's National Center for Biotechnology Information] Bookshelf at https://www.ncbi.nlm.nih.gov/books/NBK501922/ [(LactMed® Bookshelf website)]." *Fact Sheet*, Drugs and Lactation Database (LactMed®), Bethesda, MD, NICHHD (2006 to [present and regularly updated]), available at https://www.ncbi.nlm.nih.gov/books/NBK547437. In addition, the LactMed® Bookshelf website indicates that a "peer review panel reviews the data to assure scientific validity and currency."

Proposed new N.J.A.C. 8:75-4.1(c)5 and 4.2(a)8 would require an RA-HMB's medical director, informed by LactMed®, to respectively screen, and/or determine to exclude from donating, a donor who uses contraindicated substances. In contrast to LactMed®, *Hale's Medications [and] Mothers' Milk*, which is both a publication and website, must be purchased in hard copy or accessed online by paid subscription. See Thomas W. Hale, RPh, PhD, et al., *Hale's Medications & Mothers' Milk 2025-2026: A Manual of Lactational Pharmacology,* (21st Edition), and https://www.halesmeds.com (hereinafter collectively referred to as *Hale's*). The InfantRisk Center, which Dr. Hale founded in 2011, is an educational and research institution with a clinical pharmacology laboratory and call center at the Texas Tech University Health Science Center School of Medicine in Amarillo, Texas, which also maintains a website. See Texas Tech University Health Sciences Center, *About the InfantRisk Center* (2025), available at https://www.infantrisk.com/about-infantrisk-center.

The Department declines to require an RA-HMB to purchase a subscription to the *Hale's* publication and/or website, particularly when an appropriate United States government-issued resource is available at no cost. The medical director of an RA-HMB, in the exercise of informed clinical judgment, may elect to consult resources in addition to LactMed®, such as *Hale's* and those that the *InfantRisk Center* makes available. However, in performing oversight of RA-HMBs, the Department will treat LactMed® as generally controlling. Based on the foregoing, the Department will make no change upon adoption in response to the comments.

41. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(c)11, a commenter states that "HMBANA Standards for travel have been updated to reflect a screening emphasis

for travel in the previous year." The commenter recommends "that this requirement be updated to reflect the current HMBANA standard." (2)

42. COMMENT: A commenter states that proposed N.J.A.C. 8:75-4.1(c)11 "is extremely broad and it's not clear how a deferral would be determined based on a broad category like this. It is also not aligned with the most current safety data. HMBANA eliminated this question in [its] most recent (2023) standards. Now the travel questions in HMBANA screenings focus on more recent travel in the past year." (6)

RESPONSE TO COMMENTS 41 AND 42: Proposed N.J.A.C. 8:75-4.1(c)11 would require an RA-HMB to consider and evaluate a human milk donor candidate's travel history in screening the candidate, including time spent on an overseas military base. In contrast, proposed new N.J.A.C. 8:75-4.2, especially at paragraph (a)12, would establish criteria for nonnegotiable exclusion of a donor based on that donor's travel history. The Department agrees that proposed new N.J.A.C. 8:75-4.1(c)11 would establish a broad disclosure standard with respect to a donor candidate's travel history. The Department intends proposed new N.J.A.C. 8:74-4.1(c)11 to prompt a conversation during screening that might elicit information about infectious diseases or environmental conditions to which a donor candidate might have been exposed during travel that could be relevant in determining whether it would be appropriate for the RA-HMB to accept the candidate as a human milk donor for vulnerable infants.

Knowledge concerning the etiology of diseases and conditions that might affect human milk continually increases and evolves. An RA-HMB medical director's awareness of a donor candidate's travel during screening might identify indicators of potential exposures that could

contraindicate acceptance of the candidate as a donor or disclose concerns warranting additional investigation.

For example, a discussion about the service abroad of a veteran of one of the branches of the United States military could produce information about the veteran's exposure to burn pits, the long-term impact of which on humans (and perhaps, on human milk) is both difficult to prove and an evolving area of medical research and knowledge. See, for example, American Cancer Society, "Military Burn Pits and Cancer Risk" (2025), available at https://www.cancer.org/cancer/risk-prevention/chemicals/burn-pits.html (ACA burn pit factsheet), and Adamson M, Assefa M, Grewal D, et al., "Long-Term Reproductive Health Outcomes in Women Veterans Exposed to Airborne Hazards and Open Burn Pits," *Archives of Physical Medicine and Rehabilitation*, Volume 105, Issue 4, e26 (April 2024), available at DOI: 10.1016/j.apmr.2024.02.071 (describing a questionnaire that the Women's Operations Military Exposure Network of the War Related Illness and Injury Study Center of the Veterans' Administration (VA) is using "to assess toxic exposures during military deployment and subsequent health outcomes among women Veterans [and thereby collect data that would enable the VA] to examine relationships between military service, deployment, exposures, and women-specific health issues").

While a veteran's service in the Afghanistan and Gulf War theaters of operation might make the veteran presumptively eligible for PACT Act healthcare disability benefits (see ACA burn pit factsheet), neither proposed new N.J.A.C. 8:75-4.1(c)11 nor 4.2 automatically would disqualify that same veteran as a human milk donor because of that veteran's travel to those places. However, identifying that travel as part of donor candidate screening could elicit facts about the veteran's environmental or biological exposures that an RA-HMB medical director, in

consideration of evolving health research, might find to be contraindicative of the appropriateness of acceptance of that candidate as a human milk donor for vulnerable infants. Therefore, the Department will make no change upon adoption in response to the comments.

43. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(d), a commenter states that “medical sign off is no longer a component of HMBANA’s requirements [because] it has proven to be a time-consuming process and did not provide specific details that assists with the donor’s screening process. The focus instead is on the donor’s own provider’s sign off. Therefore, [the commenter] request[s] that the requirement for an infant’s healthcare provider sign off be removed from the [proposed new rules].” (2)

44. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(d), a commenter states that “HMBANA no longer requires signed letters due to low value and high administrative burden,” and recommends that the Department instead require RA-HMBs to “[n]otify pediatricians, but do not require written confirmation for non-compensated donors.” (4)

45. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(d), a commenter states that “the written statement from the donor infant’s healthcare provider requirement has been lifted by HMBANA due to the difficulty in obtaining with virtually no yield of important information.” [The HMB that the commenter represents] is located in Pennsylvania where this is still a requirement and “… believes that overall, there is value in having the pediatrician of the donor’s baby aware that the mother is donating milk. Confirmation from the pediatrician that the donor’s infant is receiving enough maternal milk is important when donor remuneration is involved and especially in volume[-]based donor compensation models.” [The commenter] “suggests that milk banks that do not compensate donors (all … HMBANA[-]accredited milk

banks) [be] only required to notify the pediatrician that the mother is a donor and provide contact information for the milk bank if the pediatrician has any questions or concerns. This approach would alleviate unnecessary delays in screening but still alert the baby's healthcare provider." (5)

46. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(d), a commenter states that "[r]equiring written approval of donation by donor baby's doctor … has been determined by HMBANA standards to be an unnecessary step and one that is very hard to implement as getting doctors to fill out these forms is burdensome. [The commenter's] prior experience with this requirement shows that it significantly slows the process and limits the possible milk bank donors while not increasing the safety or wellbeing of either the donor baby or the recipient babies. This requirement would limit the amount of donor milk we could make available to New Jersey substantially. [The commenter] recognize[s] that the rationale for such a requirement could be to ensure that a biological baby receives maternal milk prior to any milk being donated, a public health tenet … with [which the commenter agrees] entirely. For nonprofit HMBANA[-]accredited milk banks, the absence of financial compensation for donor milk reduces, if not eliminates this risk. Thus [the Department] might consider a different approach and only require a pediatrician's approval if the milk bank compensates donors." (6)

RESPONSE TO COMMENTS 43, 44, 45, AND 46: Proposed new N.J.A.C. 8:75-4.1(d) would require an RA-HMB, regardless of its stance on donor compensation, to obtain a written statement from the healthcare professional who treats the donor's infant that addresses various factors relating to the impact of a donor candidate's status as a human milk donor on the donor's infant. The Department intends proposed new N.J.A.C. 8:75-4.1(d) to ensure that a donor's contribution of DHM, regardless of motivation or incentive, does not occur at the

expense of the health of the donor's infant, in the opinion of that infant's health care provider. The Department does not intend the proposed new rules to necessarily track HMBANA's accrediting standards. As the Department develops experiential and anecdotal data in administering RA-HMB oversight, it will consider whether it would be appropriate to waive proposed new N.J.A.C. 8:75-4.1(d) with respect to an RA-HMB that does not financially compensate its donors. Therefore, the Department will make no change upon adoption in response to the comments.

47. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(e), a commenter states that "[r]equiring repeat blood work every [three] months will significantly increase the cost of acquiring milk donations for milk banks and more impactfully, will be a deterrent to potential donors given the time and effort requirement. New York State currently requires repeat blood work every six months and that has at times proven to be burdensome for donors." The commenter "request[s] this be revised, at a minimum to align with New York State's [six-]month requirement or removed entirely as a requirement unless a repeat test is warranted due to a change in health status." (2)

48. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(e), a commenter states that requiring "[s]erological [t]esting [e]very [three m]onths … is excessive and deters continued donation." The commenter recommends that the Department "[e]liminate repeat testing unless health status changes. If required, extend the interval to [six] months." (4)

49. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(e), a commenter states that "[r]epeating blood work every three months will greatly diminish the milk supply for nonprofit milk banks and increases costs. The HMBANA guidelines are tailored to the specific

business model of nonprofit milk banking which includes a low[-]risk, unremunerated donor pool. HMBANA does not require repeat blood work in the absence of an exposure or change in health status. Three months is also a very short interval and most donors would be impacted. It is likely that many will decide not to bother repeating blood work required for continuation as a milk donor. At the [three] month mark, donors will have contributed the minimum asked for by the milk bank ([the minimum the HMB that the commenter represents being] 150 total ounces) and are likely to just share milk in the community instead. New York is the only state that requires repeat blood work and the interval is [six] months. [The HMB that the commenter represents] performed repeat bloodwork at [six-]month intervals in the past to fulfill New York requirements [and a]fter following this practice for a number of years and never encountering a positive test in bloodwork repeated at [six] months … changed its procedure to follow HMBANA's current guideline. On the rare occasion of distribution to New York, only milk that fulfills all New York requirements is sent." (5)

50. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(e), a commenter states that "[r]equiring that bloodwork be repeated every three months *will limit available milk in NJ significantly*. HMBANA guidelines do not require repeat serological testing in the absence of exposure or change in health status (something that is reviewed every two months). These guidelines have resulted in an excellent safety record spanning several decades. By requiring repeat serological testing every three months, the majority of milk donors will be impacted, and [the commenter] expect[s] that many will choose not to comply given the inconvenience. *This means that a significant portion of [the] pasteurized milk supply [of the HMB that the commenter represents] will be deemed 'not for New Jersey' and [New Jersey] hospitals and families will likely experience inconsistent availability for their needs*. Additionally, the expense

of additional blood testing is significant for nonprofit milk banks, and some may choose to simply limit the New Jersey milk supply. New York is the only state that requires repeat bloodwork, and it is required every six months. Importantly, New York's regulations are quite dated, drafted in 2000[. The] states that have developed more recent regulations recognize the long history of safe donor milk supplies from HMBANA[-]accredited milk banks and have not included this provision." [(Emphasis in original.)] (6)

RESPONSE TO COMMENTS 47, 48, 49, AND 50: The requirement that a donor repeat serological testing every three months is intended to ensure that a donor does not unwittingly or unknowingly donate milk while infected with one of the diseases for which serological testing is required. However, the Department is aware that repeat serological testing of donors every six months is considered a best practice. Unger S, O'Connor DL, "Review of current best practices for human milk banking", *Matern Child Nutr.* 202420:(S4), e13657, available at https://doi.org/10.1111/mcn.13657 (providing a composite of human milk banking best practices from published guidelines from Australia, Brazil, France, India, Italy, Spain, the United Kingdom of Great Britain and Northern Ireland, the European Milk Bank Association, and HMBANA). The Department does not wish the proposed new rules to unduly impede donation or decrease the supply of DHM in the State. At the same time, even if a donor's screening reveals no cause for concern, there is no way to ensure that during the interval between repeat serological testing, a donor's sexual partner refrains from behaviors that could result in the donor's infection with a disease that would require the donor's exclusion. The Department will refer this issue for further review to its experts in HIV, STD, and TB, epidemiology, and communicable disease, and other relevant stakeholders. Upon obtaining the recommendation of these experts, the Department will determine whether to promulgate an

amendment at proposed new N.J.A.C. 8:75-4.1, to change the spacing interval between repeat serological testing in a future rulemaking.

N.J.A.C. 8:75-4.2 Donor Exclusion and Deferral Criteria

51. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.2(a)9, a commenter states that "HMBANA standards allow … vegetarians and vegans to donate without the requirement of vitamin B12 supplementation. Therefore, [the commenter] request[s] removing this as a reason for deferral." (2)

52. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.2(a)9, a commenter states that "[e]xclusion of [vegan and vegetarian] donors is unnecessary under current HMBANA guidelines" and recommends that the Department "[r]emove this exclusion." (4)

53. COMMENT: A commenter states that "[v]egetarians do consume sources of B12 (eggs, dairy, etc.) and do not need supplementation." (5)

54. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.2(a)9, a commenter states that "[deferral of a] vegetarian or vegan [donor candidate who does] not take Vitamin B12 supplements … is not aligned with any standard or clinical expertise on donor milk [with which the commenter] is familiar [and that the HMB the commenter represents] generally pools milk from multiple donors for nutritional optimization." (6)

RESPONSE TO COMMENTS 51, 52, 53, AND 54: Proposed new N.J.A.C. 8:75-4.2(a)9 would require exclusion as a donor of a person who abstains from consumption of animal products and does not take vitamin B12 supplements. Upon reconsideration of N.J.A.C. 8:75-4.2(a)9, the Department acknowledges that pooling DHM during processing may alleviate concern related to vitamin B-12 deficiency in DHM collected from a donor who abstains from consuming animal products, and that HMBs (regardless of nonprofit or accreditation status)

typically perform DHM-pooling during processing. Based on the foregoing, the Department will make a change upon adoption at proposed new N.J.A.C. 8:75-4.2(a)9 to state that an RA-HMB need not exclude a donor who abstains from consuming animal products if the RA-HMB that will process collected DHM engages in DHM pooling during processing. The Department notes a recent study of PHM of a large Canadian milk bank, showing that, even when most donors (over 93 percent) were consumers of animal products and pooling was used in processing, PHM nonetheless may provide vitamin B12 at *suboptimal* levels for infants of very low birthweight (VLBW). Greco, A, Baxter, J-A B, et al., "Vitamin B12 concentrations vary greatly in milk donated to a large provincial milk bank, and are influenced by supplementation and parity" (January 2025) *Clinical Nutrition*, *44*, 19–24 available at https://doi.org/10.1016/j.clnu.2024.11.027 ("Further research is needed to understand optimal vitamin B12 concentrations supportive of healthy infant growth and development, especially among VLBW infants who face increased risk of neurodevelopmental impairment, [and] to determine optimal dietary and supplementation recommendations for milk bank donors."). The Department will continue to monitor research addressing optimal vitamin B12 concentrations for VLBW infants consuming DHM with a view towards future rulemaking as may be indicated.

55. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(a)9 and 11 and 4.2(a)5 and 12, a commenter states that "[s]ome criteria (e.g.[,] tattoos, travel) do not reflect current HMBANA standards" and recommends that the Department "match latest HMBANA guidelines." (4)

56. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(a)9 and 11 and 4.2(a)5 and 12, a commenter states that "[m]any of the criteria listed pertaining to bloodborne

pathogen exposure including the receipt of tattoos, travel, and living abroad have been modified by HMBANA due to the newest data. It appears that some of these criteria are from older editions of the HMBANA standards and are no longer considered best practices." (5)

57. COMMENT: With respect to proposed new N.J.A.C. 8:75-4.1(a)9 and 4.2(a)5, a commenter states that "HMBANA standards only require deferral if tattoos, piercings, or application of permanent make up was not performed with sterile, single use needles" and "recommend[s] this change." (6)

RESPONSE TO COMMENTS 55, 56, AND 57: Some commenters appear to conflate the screening criteria as mandatory exclusionary or deferral criteria. Proposed new N.J.A.C. 8:75-4.1 would identify the minimum information that an RA-HMB must collect in writing, discuss in a spoken interview with each donor candidate, and evaluate in considering whether to accept the candidate as a human milk donor for vulnerable infants. Proposed new N.J.A.C. 8:75-4.2 would identify criteria that mandate deferral or exclusion of human milk donor candidates.

The Department agrees that the topics that an RA-HMB must address in screening candidates are broad and intends this breadth of scope to elicit information from a donor candidate to help the RA-HMB identify factors that warrant special consideration, further investigation, deferral, or exclusion of the donor pursuant to N.J.A.C. 8:75-4.2.

As stated in the Federal Standards Statement in the notice of proposal, HMBANA's accreditation standards are proprietary and were not available to the Department in the development of this rulemaking, other than the 2024 summary that HMBANA made publicly available on its website (citation 16 of the notice of proposal). The proposed new rules at N.J.A.C. 8:75 reflect the Department's independent research and standards development. The

proposed new rules would apply to entities that are not HMBANA-accredited and would be ineligible for HMBANA accreditation because they are for-profit entities and/or compensate donors. Therefore, the commenters are correct in noting that proposed new N.J.A.C. 8:75 would not necessarily mirror the most recently issued HMBANA accreditation standards.

Proposed new N.J.A.C. 8:75-4.1(c)9i would require an RA-HMB to screen and consider, in accordance with subsection (b), a human milk donor candidate's behavioral and lifestyle history, as it might implicate infectious disease risk, including the receipt by the candidate, or the candidate's partner, of a tattoo, a piercing, or permanent makeup. Proposed new N.J.A.C. 8:75-4.2(a)5 would require exclusion of a donor whose receipt, or partner's receipt, of a tattoo, a piercing, or permanent makeup was performed in contravention of the standards at N.J.A.C. 8:27 Body Art and Ear-Piercing Facility Standards, and obtains the result of a serology test, performed at least three months after receiving the tattoo, piercing, or permanent makeup, that is positive for the conditions listed at proposed new N.J.A.C. 8:75-4.1(e) (note: the Department is making an agency-initiated change upon adoption to correct the incorrect cross-reference to N.J.A.C. 8:75-4.1(c) to refer instead to subsection (e)). Thus, proposed new N.J.A.C. 8:75-4.2(a)5 would appear to be consistent with the commenter's description of the HMBANA accreditation standard, but for the additional requirement of a negative result of a serology test performed at least three months after the performance of the body art. Based on the foregoing, the Department will make no change upon adoption in response to the comments.

N.J.A.C. 8:75-4.3 Donor Education Program

58. COMMENT: With respect to N.J.A.C. 8:75-4.3(c), a commenter states, "[a]s a HMBANA[-]accredited milk bank, [the commenter] provide[s its] donors … education related to their milk pumping, collection[,] and storage practices as well as to shipping their milk to the

milk bank. [The commenter's] emphasis is on activities related to milk banking. As nonprofit organizations with limited resources, most milk banks do not have lactation specialists on staff to provide lactation support and counseling." Therefore, the commenter "respectfully request[s] that any lactation guidance not be included as a milk bank function or requirement." (2)

59. COMMENT: A commenter states, "HMBANA education focuses on milk handling, not nutrition or lactation." The commenter recommends that the Department "[c]larify that milk banks are not required to provide nutrition or breastfeeding counseling." (4)

60. COMMENT: A commenter states that "[the commenter] and all HMBANA[-] accredited milk banks provide relevant education to donors regarding the labeling, storage, and shipping of milk along with pump cleaning and sanitization. Donors are instructed when to notify the milk bank (illness, new medications, etc[.]). Smoking, vaping and using tobacco or cannabis in any form is prohibited by HMBANA guidelines. Nutrition, smoking, and lactation education is beyond the scope of a milk bank. Many milk banks do not have nurses or lactation consultants on staff." (5)

61. COMMENT: A commenter states "[m]ilk banks should stay focused on their primary mission, ensuring safe, voluntary, incentive free donations of excess human milk. It is out of [milk banks] scope of practice to provide other types of education to the hundreds of women [the commenter and milk banks] work with, including around other important areas such as smoking. [The commenter and milk banks'] work must remain exclusively focused on safe milk donation practices and [the commenter and milk banks] do not have the capacity to provide support beyond that, including acting as lactation consultants." (6)

RESPONSE TO COMMENTS 58, 59, 60, AND 61: Proposed new N.J.A.C. 8:75-4.3 would not require an RA-HMB to employ a specialist or consultant with expertise in the topics that its donor education, at a minimum, must address. Rather, in developing its donor education program, proposed new N.J.A.C. 8:75-4.3 would require an RA-HMB to incorporate the guidance and sources of information at subsection (a) and at proposed new N.J.A.C. 8:75-1.3(c), as well as any other evidence-based information it might deem appropriate, in consultation with its medical advisory board.

For example, as noted above in response to previous comments, the infants eligible to receive PHM from an RA-HMB would include infants of very low birthweight who might receive insufficient levels of vitamin B12 from PHM, regardless of whether donors consume animal products. Thus, an RA-HMB's policies and procedures for donor education regarding nutrition might include information about vitamin supplementation to enhance the nutritional quality of DHM.

An RA-HMB's policies and procedures for donor education regarding lactation procedures might address appropriate sanitation measures prior to expression of DHM. This would appear to be consistent with the commenters' description of the donor education training they provide.

As stated in response to previous comments, and for the reasons stated therein, the commenters are correct in noting that the proposed new rules would not necessarily track HMBANA accreditation standards.

Based on the foregoing, the Department will make no change upon adoption in response to the comments.

Subchapter 5. Collection of DHM

N.J.A.C. 8:75-5.1 Collection of DHM

62. COMMENT: A commenter states with respect to proposed N.J.A.C. 8:75-5.1(c)2 that "[a]s a HMBANA[-]accredited milk bank, [the commenter] provide[s] donors with detailed instructions about how to appropriately label their milk containers to include the assigned identification number as well as their pump date and time of collection. The process is simple and [the commenter has] not received any milk donations without the required information being included by the donor. In most cases, potential donors already have a supply of milk ready for donation in containers available from their insurance companies or local stores. These containers are leak-proof BPA[-]free and sterile. Many of [the commenter's] milk donors are donating excess milk they have already pumped and stored in containers. If [the donors] were not able to donate them in their existing containers, they may not wish to donate at all. The requirement to provide containers that were prelabeled would also increase the cost for milk banks both for materials as well as staff time and also create an additional step for milk donors that could deter their willingness to donate. Therefore, [the commenter] respectfully request[s] that this requirement be eliminated." (2)

63. COMMENT: A commenter states, "[r]equiring milk banks to provide sterile, pre-labeled containers for every donor is cost-prohibitive and undermines the ability to accept milk already stored in safe, commercially available bags." The commenter recommends that the Department "[p]ermit nonprofit banks to accept previously stored milk and remove the sealed container requirement for unremunerated donations." (4)

64. COMMENT: A commenter states that "[t]his requirement would have serious supply and cost implications for nonprofit milk banks. Many donors reach out to HMBANA milk banks

after accumulating a significant amount of milk in their freezers and realizing that their child will not be able to consume it all. These volumes could be hundreds or even thousands of ounces per donor. Milk donation is not even a consideration for many of these parents prior to having this stored surplus. Not being able to accept previously stored milk in commercially available bags or vessels designed for human milk storage, but not provided by the milk bank, would also greatly inhibit the ability to capture milk that is pumped in the early weeks postpartum and by mothers of preterm and other infants hospitalized in the neonatal intensive care unit (NICU). This includes mothers who are donating milk after the death of their baby. Nonprofit milk banks keep donor milk in its natural state and this earlier milk has a nutritional and immunological profile that is particularly beneficial to NICU recipients. For-profit human milk product companies manufacture products that are manipulated to achieve certain targets and create a uniform product, so the age of milk is not a factor. The provision of sterile containers will add significant cost without demonstrated benefit. The phrase 'and seals' implies that the vessels are bottles rather than the inexpensive widely available breast milk storage bags. Bottles would add $0.30 or more to the donor milk processing fee ([the commenter's] fee is $4.50 per ounce currently). [The commenter's] milk bank has not found any difference in bacterial culture positivity rates in sterile collection bottles versus breast milk storage bags." (5)

65. COMMENT: A commenter states "[t]he vast majority of milk is pumped and stored before a woman knows that she will be in a position to donate it. The requirement for use of these prelabeled, prescribed containers is unrealistic and is not done anywhere in the country. While it is written in at least one outdated regulation, it is not implemented in practice. The combination of the added expense, logistics, and limitation of milk that is pumped after

becoming a screened donor would make milk supply in New Jersey extremely limited and there is no indication that it would provide a necessary safeguard." (6)

RESPONSE TO COMMENTS 62, 63, 64, AND 65: To enable an RA-HMB to accept DHM that a donor might have stored and collected before having established a relationship with an RA-HMB, or that the donor has collected in containers that the donor has on-hand or at no cost, such as containers of which a donor's insurance company has covered the cost, the Department will make a change upon adoption at proposed new N.J.A.C. 8:75-5.1 to allow an RA-HMB to accept DHM from a donor who uses a leakproof BPA-free container designated for the storage of breast milk. The Department will retain the requirement that an RA-HMB supply containers to a donor upon the donor's request, if the donor does not have access to containers at no cost or that are covered by a health insurer.

Subchapter 8. Distribution of DHM

N.J.A.C. 8:75-8.1 Distribution of DHM

66. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1, a commenter states that the Department should "[d]efine 'service area' more clearly. Most milk is distributed via hospitals with no direct contact between the milk bank and the recipient family. HMBANA does not assign service areas and nonprofit milk banks do not collaborate with each other to determine service areas because this would violate anti-trust laws." The commenter recommends the Department "[l]imit language requirement to outpatient services and clarify the legal basis for defining service areas." (4)

67. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1, a commenter states that "[t]he majority of donor milk distributed by nonprofit milk banks is used in the inpatient setting. Therefore, the milk banks do not have direct contact with … most recipient families.

Consenting is done by the hospitals and many health systems will not distribute educational materials from other organizations. Of note, some hospitals across the country have moved to an assent rather than consent model, especially for well-baby units. Milk banks do directly interact with outpatient recipients." The commenter inquires "[w]hat is considered a service area? HMBANA[-]accredited milk banks are separately incorporated nonprofit organizations. HMBANA does not assign service areas and nonprofit milk banks do not collaborate with each other to determine service areas because this would violate anti-trust laws." (5)

68. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1, a commenter states, "[f]or [an] outpatient population who obtain donor milk directly from [a] milk bank, consent may be reasonable (although it is likely unnecessary given safety records of HMBANA[-]accredited donor milk). If consent is required, [the commenter has] no means of 'ensuring comprehension.' [The commenter also has] no means to knowing [sic] what native language they might require. [United State of America] residents can obtain donor milk from any milk bank they choose[;] there are not designated service areas (which would be prohibited under anti-trust laws). While [the commenter] can provide consents in one or two of the most commonly spoken languages in the Northeast, [the commenter does] not have the financial resources to provide translations into multiple languages. Furthermore, [the commenter's] experience is that these documents are rarely read and therefore would not be a strong use for financial resources. Donor milk from HMBANA[-]accredited milk banks has an extremely high and sustained safety record and families who are directly ordering donor milk from [HMBANA-accredited] milk bank are doing so voluntarily." The commenter "recommend[s] dropping this requirement." (6)

RESPONSE TO COMMENTS 66, 67, AND 68: Proposed new N.J.A.C. 8:75-8.1(b) would apply to "an RA-HMB that distributes DHM *directly to a recipient who is a parent*." Therefore, the commenters' concerns, regarding the applicability of proposed new N.J.A.C. 8:75-8.1(b) when distribution of PHM occurs through an intermediary, are unwarranted.

New Jersey is ethnically diverse and many residents' primary language is other than English. The Department intends the term "service area" to mean the people of New Jersey to whom an RA-HMB provides services. If an RA-HMB provides services to out-of-State residents, the Department assumes that the laws of that state would apply to the distribution of PHM to that state's residents, with respect to the distribution of informational materials as to the risks of an infant's consumption of DHM.

Proposed new N.J.A.C. 8:75-8.1(b) would require an RA-HMB to undertake "reasonable efforts" to ensure that a parent, to whom the RA-HMB directly distributes PHM, understands the information the RA-HMB is to provide relating to the risks of an infant's consumption of DHM. It might be reasonable for an RA-HMB that distributes PHM to New Jersey residents through a face-to-face interaction to discern the parent's preferred language, and discuss the risks of an infant's PHM consumption, during that interaction. It might be reasonable for an RA-HMB that distributes PHM to New Jersey residents other than through a face-to-face interaction, such as by mail delivery, to identify the parent's preferred language in which to communicate during the first interaction with the parent, such as in an initial order form, or by means of a follow-up telephone call, during which the RA-HMB can discuss the risks of an infant's PHM consumption with the parent. If 10 percent of the parents of an RA-HMB's New Jersey resident infant clients would prefer to communicate in a language other than in English,

proposed new N.J.A.C. 8:75-8.1(b) would require the RA-HMB to translate its informational materials into that language.

In developing its written informational materials, an RA-HMB might undertake steps to ensure that its materials are written in a user-friendly way, or to provide a list of frequently asked questions (FAQs). While it might be difficult to ascertain absolutely whether a parent comprehends the informational materials an RA-HMB distributes, it might constitute a reasonable effort under the circumstances of a particular encounter for the RA-HMB, after giving a parent an opportunity to review the informational materials, to provide the parent an opportunity to ask questions concerning the risks of consuming DHM, and/or provide a telephone number for questions that might later occur to the parent.

To address the commenters' concerns regarding their understanding of the meaning of the term "service area," the Department will make a change upon adoption at proposed new N.J.A.C. 8:75-8.1(b) to delete the term "service area" and replace it with the requirement that an RA-HMB provide translated written informational materials in another language if it is the primary language of the parents of 10 percent of an RA-HMB's New Jersey resident infant clients. To address circumstances in which a Department-licensed health care facility operates an RA-HMB that distributes PHM to its patients, the Department will make a change upon adoption to require such a facility to elect to disseminate the informational material that proposed new N.J.A.C. 8:75-8.1 requires in accordance with either N.J.A.C. 8:75-8.1 or the facility's existing policies and procedures for dissemination of notices as required by applicable Department licensing standards. See, for example, N.J.A.C. 8:43E-10.3 (defining "informed consent" for purposes of implementation of the Patient Safety Act); 8:43G-4.1, Patient rights (requiring a hospital to issue each patient a written summary of patient rights and other

hospital policies and procedures in the patient's native language if 10 percent or more of the population in the hospital's service area speak that language); and 8:43G-5.2, Administrative and hospital-wide policies and procedures (requiring a hospital to establish policies and procedures for obtaining patient's informed consent to treatment).

69. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1(c)5, a commenter requests "clarification regarding prescriptions -- are prescriptions going to be a requirement? Would [the Department consider] recommend[ing] but not mandat[ing] prescriptions? Alternatively, it would be helpful to allow an initial dispensing of a small volume (40 [to] 60 ounces) to address immediate need while the family prepares for their first pediatrician's visit and the opportunity to obtain a prescription." (2)

70. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1(c)5, a commenter "support[s] the requirement for prescriptions to ensure that babies with a medical need are prioritized." The commenter recommends that the Department "[a]llow for a small bridge volume (e.g., 50-60 [ounces]) to be dispensed without a prescription immediately post-discharge." (4)

71. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1(c)5, a commenter states that "[a] prescription is required for outpatient use [and] support[s] this decision because it places determination of the medical need for donor milk on the healthcare provider that is caring for the recipient child. Donor milk is an ample, but not endless, resource and a prescription is a tool to ensure that babies with a medical need are prioritized. A prescription is required by insurers as part of the law to mandate coverage so nearly all infants with a medical need for donor milk will have a prescription in place.

A provision to allow … a small volume of outpatient donor milk to be released without a prescription, perhaps 50 [to] 60 ounces, would eliminate barriers for newborns. Many hospitals are expanding donor milk use to well newborns who need some supplementation before discharge, a practice often referred to as bridge milk because it is a bridge to success. Such use supports microbiome formation and is associated with higher rates of eventual maternal exclusive breastfeeding. Sometimes the need for donor milk extends for a few days after discharge. Allowing for this small amount meets the immediate needs until the first pediatrician appointment.

Elective (non-medical need) use beyond bridge milk should include the guidance of the health care provider. The clinician that is caring for the baby is best equipped to educate about formula and donor milk and help the family determine the most appropriate nutritional plan for their child. Of note, requests for outpatient donor milk are dependent on supply. HMBANA requires milk banks to have triage plans in place to prioritize NICUS first in times of increased demand followed by outpatients with a documented medical need to ensure that the sickest children are receiving this vital resource." (5)

72. COMMENT: With respect to proposed new N.J.A.C. 8:75-8.1(c)5, a commenter states that "many states are eliminating [the] prescription requirement [for outpatient donor milk], recognizing that it creates unnecessary barriers to donor milk access particularly for underserved populations. Those that do require a prescription allow … at least 40 ounces of donor milk without a prescription to ensure uninterrupted feeding post-hospital newborn discharge. If [the Department] decide[s] to [retain] this requirement, [the commenter] urge[s] [the Department's] partnership to educate medical prescribers that donor milk is a limited resource that is prioritized for medically fragile hospitalized babies. Thus, writing a prescription

does not guarantee that donor milk will be available for healthy babies or in the amounts requested."

With respect to "[p]rioritizing [m]edically [f]ragile [b]abies," the commenter states that "HMBANA accreditation requires [an HMB to] triage donor milk for medically fragile babies in hospital NICUs" and that the Department "might consider this requirement to ensure that profit-based milk banks don't siphon away the limited resources of donor milk and use it for other purposes that could increase their bottom lines while making it harder to ensure that babies who require donor milk to protect their health and guard against the potentially fatal complication of necrotizing enterocolitis do not have adequate supplies." (6)

RESPONSE TO COMMENTS 69, 70, 71, AND 72: N.J.S.A. 26:2A-17 limits the distribution of DHM by an RA-HMB: "[1] to a hospital for use by low birth weight babies or new mothers with delayed lactation, or [2] 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." Accordingly, the Department is without discretion to modify the entities to whom, and the conditions under which a hospital or an RA-HMB would be authorized to distribute PHM. Therefore, the Department will make no change upon adoption in response to the comments.

Summary of Agency-Initiated Changes Upon Adoption:

The Department is making a change upon adoption at proposed new N.J.A.C. 8:75-3.6(a) to require an RA-HMB to notify the BCP within 24 hours (and preferably immediately), at the BCP electronic mail address, rather than by telephone, upon its discovery of an event of the type at proposed new N.J.A.C. 8:75-3.6(a)1 through 5.

The Department is making non-substantial changes upon adoption to correct internal cross-references, maintain consistent use of defined terms, and note a registered trademark, where required.

The Department is making a change upon adoption to the chapter appendix at the "HMB and Operator Information" part of the form, at which an applicant indicates the services for which it is applying for registration and accreditation to provide, to add "donor selection" to conform to the list of human milk bank services in the definition of "human milk bank" at N.J.S.A. 26:2A-17. In addition, to correspond with the additional fee category the Department is establishing, as stated in the Response to Comments 12, 13, and 14, the Department is adding a line to the "Application" part of the form to enable an applicant to indicate that it is applying for registration and accreditation as an authorized location of an HMB that only receives and temporarily stores raw frozen donor milk before it is sent to the HMB for processing.

Federal Standards Statement

(**Agency Note**: The citations listed herein by number in parentheses refer to the List of References that appear in the notice of proposal at 57 N.J.R. 796(a) at 802-803.)

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 adopted 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 adopted new rules would condition Department registration and accreditation on compliance with applicable Federal standards as a minimum standard. Therefore, the adopted new rules would meet, but not exceed, 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 adopted new rules.

Except as described above, the Department is adopting 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.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

CHAPTER 75

HUMAN MILK BANK REGISTRATION AND ACCREDITATION

SUBCHAPTER 1. GENERAL PROVISIONS

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:

...

"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*[.]*****, and includes a person who is eligible for:**

1. Licensure by reciprocity as a physician pursuant to N.J.A.C. 13:35-3.2;

2. Certification by endorsement as an advanced practice nurse pursuant to N.J.A.C. 13:37-7.6; or

3. Licensure as a physician assistant pursuant to N.J.A.C. 13:35-2B.5.*

...

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

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]* ***$1,000***
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]* ***$1,000***
Initial registration and accreditation of an authorized location of an HMB that only receives and temporarily stores raw frozen donor milk before it is transported to an HMB for processing	***$500.00***

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]* ***$1,000***
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]* ***$1,000***
Annual renewal of registration and accreditation of an authorized location of an HMB that only receives and temporarily stores raw frozen donor milk before it is transported to an HMB for processing	***$500.00***

(b)-(c) (No change from proposal.)

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)]* ***May 18, 2026*** to be a provisionally registered and accredited HMB (PRA-HMB) and thereby authorized to continue existing operations in the State without interruption; provided:

1. (No change from proposal.)

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)]* ***June 17, 2026***, 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)]* ***July 17, 2026***.

(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 nticipated 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)-(b) (No change from proposal.)

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

(d) (No change from proposal.)

8:75-3.4 Required policies and procedures

(a)-(b) (No change from proposal.)

(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.-10. (No change from proposal.)

11. Establishment and dissemination of written instructions to inform a parent as to proper handling, storage, ***and*** preparation ***of PHM***, and *[disposal upon expiration]* ***the need to dispose*** of***, and not feed an infant, spoiled or improperly handled*** PHM;

12.-14. (No change from proposal.)

8:75-3.6 Reportable events

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

1.-5. (No change from proposal.)

(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. (No change from proposal.)

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

i. (No change from proposal.)

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]* ***using*** the application form at N.J.A.C. 8:75 Appendix.

8:75-3.7 Responsibility for delegated services*[.]*

(a)-(b) (No change from proposal.)

SUBCHAPTER 4. DONOR SELECTION AND TRAINING

8:75-4.1 Donor identification, screening, and *[qualification]* ***selection***

(a)-(f) (No change from proposal.)

(g) In accordance with its policies and procedures and the CDC *[donor]* ***breastfeeding*** 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.] ***1.*** In accordance with the criteria at N.J.A.C. 8:75-4.2; and/or

[ii.] ***2.*** 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)-(k) (No change from proposal.)

8:75-4.2 Donor exclusion and deferral criteria

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

1.-4. (No change from proposal.)

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)]* ***4.1(e)***, at least three months after the piercing, tattoo, or permanent makeup application, obtains a positive result on any test;

6.-8. (No change from proposal.)

9. Is a vegetarian or vegan and does not take vitamin B12 supplements***, unless the RA-HMB that will process collected DHM engages in pooling of DHM during processing***;

10.-16. (No change from proposal.)

(b)-(c) (No change from proposal.)

(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]* ***policies and procedures*** it establishes pursuant to N.J.A.C. 8:75-3.4(a)1 to determine:

1.-2. (No change from proposal.)

(e)-(f) (No change from proposal.)

8:75-4.3 Donor education program

(a)-(b) (No change from proposal.)

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

1.-7. (No change from proposal.)

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

9. (No change from proposal.)

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]* ***the RA-HMB's*** policies and procedures.

(b) (No change from proposal.)

(c) An RA-HMB shall:

1. (No change from proposal.)

2. *[Supply pre-sterilized, leak-proof containers and]* ***Subject to (c)3 below, exclusively accept from a donor DHM that was stored upon expression in a leakproof bisphenol A-free*** container *[seals to each donor, on which the RA-HMB has affixed a tag or label]* ***designated for the storage of breast milk*** on which *[the]*:

i. The* donor *[is to specify]* ***specifies*** the date of expression and *[providing:

i. The]* ***the*** donor's RA-HMB identification number; and

ii. *[A space wherein the]* ***The*** RA-HMB is to indicate the date and time of collection from the donor*[.]*****; and**

3. Upon request of a donor who does not have access to storage containers of which the cost is covered by a third party, such as a health insurance benefits provider, supply leakproof BPA-free containers designated for the storage of breast milk to the donor for that donor's prospective use to store expressed human milk for donation to the RA-HMB.*

(d)-(e) (No change from proposal.)

SUBCHAPTER 8. DISTRIBUTION OF DHM

8:75-8.1 Distribution of DHM

(a) (No change from proposal.)

(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 ***the primary language of at least 10 percent of the parents to whom an RA-HMB directly distributes PHM on behalf of a New Jersey resident infant client, is*** 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]* ***statement that (b) above requires,*** translated into that language, and in English.

***2. A health care facility that the Department licenses pursuant to N.J.A.C. 26:2H-1 et seq., the Health Care Facilities Planning Act (HCFPA), which operates an RA-HMB**

and distributes PHM to its patients, shall provide the notice that this section requires in accordance with either:

i. Applicable policies and procedures for issuance of notices to patients and their families that the HCFPA requires the facility to establish and implement; or

ii. This section.*

(c) (No change from proposal.)

APPENDIX

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

Applicant is an authorized location of an HMB that only receives and temporarily stores raw frozen donor milk before it is sent to the HMB for processing

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)?

Donor Selection ☐ 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: