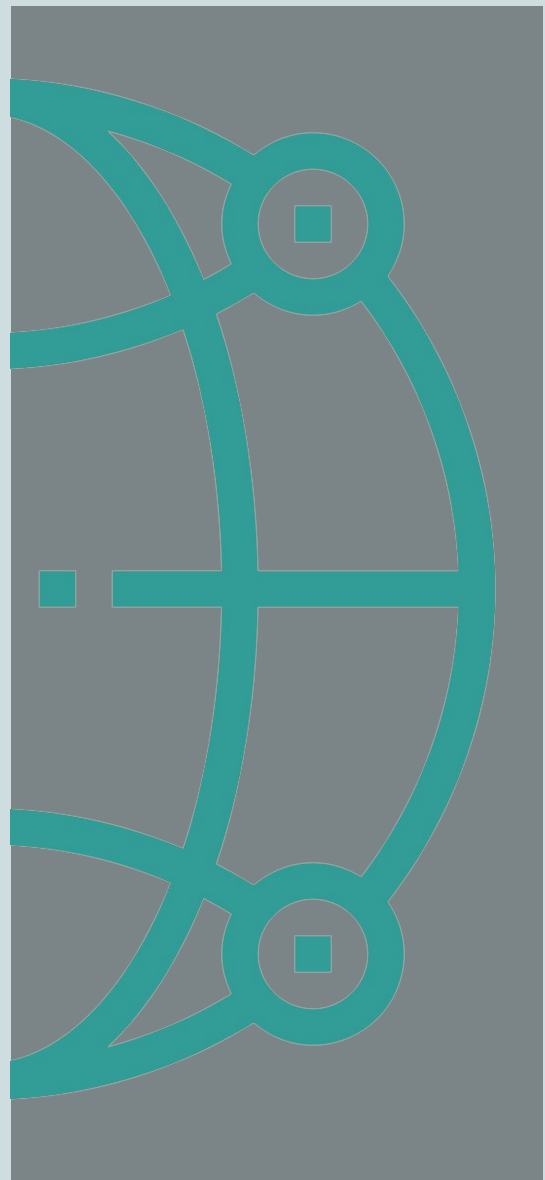


Significant Legislative Rule Analysis

Chapter 246-720 WAC
a Rule Concerning Donor
Milk Bank Standards.



February 2023



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SECTION 1

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed.

The Department of Health (department) is proposing a rule to establish standards to ensure the safety of human milk donated to milk banks, as well as the use of human milk derived products. The proposed rule incorporates the standards established by the Human Milk Bank Association of America (HMBANA), which is considered a national consensus standard, as well as additional requirements to ensure that donor human milk and human milk derived products are safe for consumption by medically fragile infants in inpatient settings.

The Legislature passed Engrossed Second Substitute Senate Bill (E2SSB) 5702 (chapter 236, Laws of 2022) , which requires the department to develop minimum standards to ensure milk bank safety for human milk and human milk derived products prescribed for inpatient use.

Human milk is an important source of nutrition and is often the first food consumed by infants after birth. This important food source is not available to all infants due to a variety of reasons. For example, not all parents or guardians are capable of producing sufficient milk to feed an infant. In such circumstances, a parent or guardian may choose to supplement their milk supply with donated human milk. Milk banks are organizations that engage in the procurement, processing, storage, distribution or use of human milk contributed by donors. Milk banks are currently not regulated in the State of Washington and there are currently no milk banks located within the State of Washington. Facilities that provide donor human milk or human milk derived products for inpatient use currently import them from out of state.

SECTION 2

Significant Analysis Requirement

As defined in RCW 34.05.328, portions of the rule require significant analysis because they adopt substantive provisions of law, the violation of which subjects a violator to a penalty or sanction.

The following SA Table 1. identifies rule sections or portions of rule sections that have been determined exempt from significant analysis based on the exemptions provided in RCW 34.05.328(5) (b) and (c).

SA Table 1. Summary of Sections not requiring Significant Analysis

WAC Section and Title	Description of Proposed Changes	Rationale for Exemption Determination
WAC 246-720-001 Purpose and Applicability.	Purpose of rule described	RCW 34.05.328(5)(c)(ii) - Interpretive language that sets rule structure.

WAC 246-720-010 Definitions.	Defines terms used throughout the rule	RCW 34.05.328 (5)(c)(ii) Interpretive language that sets rule structure.
WAC 246-720-020 Milk Bank Organizational Structure.	Describes the basic structural components of a milk bank.	RCW 34.05.328(5)(b)(iii) -- rules adopting or incorporating by reference national consensus codes that generally establish industry standards. The Human Milk Bank Association of America is considered a national consensus standard.
WAC 246-720-040 Milk Handling Restrictions.	Describes the temperature conditions required for donated milk prior to donation and for storage purposes.	RCW 34.05.328(5)(b)(iii) -- rules adopting or incorporating by reference national consensus codes that generally establish industry standards. The Human Milk Bank Association of America is considered a national consensus standard.
WAC 246-720-060 Milk Bank Standard Operating Procedures.	Describes the standard operating procedures each milk bank must develop in order to operate.	RCW 34.05.328(5)(b)(iii) -- rules adopting or incorporating by reference national consensus codes that generally establish industry standards. The Human Milk Bank Association of America is considered a national consensus standard.

SECTION 3

Goals and objectives of the statute that the rule implements.

The Legislature passed E2SSB 5702, which requires health plans and Medicaid to provide coverage for donor human milk and human milk derived products prescribed for inpatient use. The bill also requires the department to develop minimum standards to ensure milk bank safety for human milk and human milk derived products.

Research shows that access to human milk improves health outcomes for infants, including a reduced risk of infections and sudden infant death syndrome. The intent of the legislation is to provide access to human milk and human milk derived products for the state’s medically fragile infants and to ensure safety of human milk and human milk derived products. Milk banks are organizations that engage in the procurement, processing, storage, distribution or use of human milk contributed by donors. The proposed rule establishes safety standards for ensuring human milk and human milk derived products from milk banks is safe and addresses donor screening, testing, milk handling and processing, and record keeping as required by the statute.

SECTION 4

Explanation of why the rule is needed to achieve the goals and objectives of the statute, including alternatives to rulemaking and consequences of not adopting the proposed rule.

E2SSB 5702 requires the department to “adopt standards for ensuring milk bank safety.” Rules are necessary to create enforceable standards to ensure that donor milk prescribed for use in inpatient settings is safe for consumption by medically fragile infants. In the absence of rules concerning safety standards for milk banks, insurance carriers may be unable to determine whether to provide coverage for human milk or human milk derived products prescribed for inpatient use.

SECTION 5

Analysis of the probable costs and benefits (both qualitative and quantitative) of the proposed rule being implemented, including the determination that the probable benefits are greater than the probable costs.

Milk banks that are accredited by HMBANA are considered national consensus codes that establish industry standards. Under RCW 34.05.328(5)(b)(iii) these standards are exempt from analysis. See Section 2 above. In the following WAC sections or parts of WAC sections (below) the department has analyzed potential costs and benefits that are external to HMBANA standards, and therefore do not fall under the exemption.

WAC 246-720-030 Screening Milk Donors.

Description: The proposed rules in this section differ from HMBANA standards by requiring that donors be provided information in a language of the donor’s choice, rather than making a language accommodation when possible. All other standards proposed in this section are the same as required by HMBANA and are exempt from analysis under RCW 34.05.328(5)(b)(iii).

Cost(s): The department estimates translation services on average to be \$603 per language; which is the cost of 6 pages of translated documents (2,875 words) based upon estimates supplied to the department by contractor.¹ Several of the most commonly spoken languages, other than English, in Washington state include Spanish and Spanish Creole, Chinese languages such as Mandarin, Vietnamese, and Russian.² As it is unknown which of these languages will be most often requested, if any, the total cost of this proposed rules in this section is indeterminate. If the most commonly spoken languages were requested this would be 5 languages which the department anticipates to cost in the range of \$2,500 - \$3,015 to comply with the requirement. The department assumes that once documents are translated, they could be reused with no additional costs, therefore making these potentially one-time costs, per language.

Benefit(s): The proposed rule ensures that information be provided to the milk donor in the language of their choice, allowing for ease of understanding and increased equity.

WAC 246-720-050 Milk Donor Education and Procedures.

Description: The proposed rules in this section differ from HMBANA standards by requiring that donors be provided information in a language of the donor’s choice, rather than making a language accommodation when possible. All other standards proposed in this section are the same as required by HMBANA and are exempt from analysis under RCW 34.05.328(5)(b)(iii).

Cost(s): See WAC 246-720-030 Screening Milk Donors (above) for the translation cost estimate.

Benefit(s): The proposed rule ensures that information be provided to the milk donor in the language of their choice, allowing for ease of understanding and increased equity.

¹ Estimate provided to the Department of Health by NWI Global (E-011360-01). [NWI Global Language Access Services, Translation, Interpreting](#). Received February 24, 2023.

² [The History of Language in Washington State \(languagenetworkusa.com\)](#)

WAC 246-720-070 Milk Bank Minimum Operating Standards.

Description: Existing HMBANA standards require milk banks to comply with the federal Food Safety Modernization Act (FSMA) and register with the US Food and Drug Administration (FDA). WAC 246-720-070 adds to these standards by requiring that milk banks provide the department access to these records upon request.

Cost(s): The department estimates the costs associated with providing these documents to be negligible as it would consist of administrative time to provide access.

Benefit(s): Provides a mechanism for the department to ensure milk banks are meeting existing federal food safety standards.

WAC 246-720-080 Milk Processing.

Description: The proposed rules in this section differs from HMBANA standards by:

- Allowing processed donor human milk to be stored not only in FDA-approved glass or plastic bottles but also can be stored in other food-grade storage containers that meet FDA standards,
- Allowing "thermal processing" as a heat treatment option, and
- Specifying that human milk derived products must comply with the Code of Federal Regulations Title 21—Food and Drugs, Chapter I—Food and Drug Administration, Department of Health and Human Services, Subchapter B – Food for Human Consumption Part 107 Infant Formula (21 CFR 107.50)³.

All other standards proposed in this section are the same as required by HMBANA and are exempt from analysis under RCW 34.05.328(5)(b)(iii).

Cost(s): The proposed rule requires processed donated human milk to be stored in FDA-approved glass or plastic bottles or other food-grade containers that meet FDA standards⁴. Milk banks are already required, by HMBANA and/or the FDA, to store processed donated human milk as described and therefore the department does not anticipate any additional costs to comply.

HMBANA standards require donor human milk to be pasteurized prior to storage. The proposed rule allows for thermal processing, which includes but is not limited to pasteurization, to heat

³21 C.F.R. § 1.107 (2022).

⁴ Center for Food Safety and Applied Nutrition. "Regulatory Status of Components of a Food Contact Material." U.S. Food and Drug Administration. FDA. Accessed March 14, 2023.

<https://www.fda.gov/food/packaging-food-contact-substances-fcs/determining-regulatory-status-components-food-contact-material>

treat the milk. Other thermal processing procedures currently used by milk banks are proprietary information and therefore the department is unable to provide a cost estimate.

Milk banks that create human-milk derived products, as regulated by the FDA, are already required to comply with federal code for infant formula and therefore the department does not anticipate any additional costs to comply.

Benefit(s): This section of the rule differs from HMBANA standards to allow for the inclusion of milk banks that create human milk derived products since their processes may differ. Including these milk banks is important to ensure that their products are safe for use with medically fragile infants in inpatient settings.

Milk banks that create human milk derived products currently use other food-grade containers, besides bottles, that meet FDA standards. Allowing this in the rule, ensures these milk banks are not excluded and that these products are safe for use with medically fragile infants in inpatient settings.

Milk banks that create human milk derived products currently heat treat donor human milk in methods that differ from pasteurization. Allowing other thermal processing methods in the rule, ensures these milk banks are not excluded and that these products are safe for use with medically fragile infants in inpatient settings.

Milk banks that create human milk derived products are regulated by the FDA under the exempt infant formula code. Requiring this in rule provides a mechanism for the department to ensure these milk banks are meeting existing federal food safety standards.

WAC 246-720-090 Additional requirements for donor human milk provided by compensated donors.

Description: The proposed rule requires an additional testing and quality assurance step for milk provided by donors who are compensated for their milk. The rule mentions two possible options for testing; one method to test for adulteration is with a human milk analyzer and another option is DNA testing. Milk banks have the option to use other methods to ensure the donated human milk is not adulterated and are not required to use any specific type of test.

Milk banks who compensate their donors have indicated in meetings with the rulemaking team that testing for adulteration is already current practice within their facilities and have advocated for this standard to be included in the rule.

Cost(s): The department analyzed the two options for testing that are called out in the proposed rule to understand potential costs:

- A human milk analyzer is a way to comply with the proposed rule requirement. The department reached out to Miras Solutions who is a supplier of an FDA-cleared analyzer (equipment) for human milk.⁵ Miras suggested that initial start-up (cost of a machine) is estimated at \$50,000, which the department annualized over the useful life of the machine (10 years) using standard depreciation (10%) including the cost of replacement of analyzer parts at year 5, resulting in the department anticipating that the first year cost of a human milk analyzer to be \$9,962. This cost would be an annual cost over the 10 years of useful life of the equipment.
- DNA testing is a way to comply with the proposed rule requirement, however the department is unable to estimate the cost because it is currently under trademark and only one company is allowed to use the technology⁶.

The department acknowledges that these are only two options for testing and there are others available for use, therefore the department has relied on the Miras Human Milk Analyzer to understand the potential cost to comply with the proposed rule.

A milk sampling technician may also be needed for analyzing the milk with an estimated salary average salary in Washington State of \$41,693⁷. It is the department’s understanding that a milk sampling technician’s scope of work would be larger than just analyzing milk samples therefore the department is unable to determine how much of the salary would be needed to comply with the proposed rule.

In summary, the department anticipates the cost of compliance with the proposed rule is indeterminate because at this time there is no single designated testing option.

Benefit(s): The benefits of testing milk from compensated donors is to ensure that the donor human milk is unadulterated and safe for use by medically fragile infants in an inpatient hospital setting.

WAC 246-720-100 Certification

Description: This section includes administrative requirements to apply for milk bank certification with the department. These costs include completing an application required by

⁵ Information provided via e-mail to the Department of Health by Miris,(Miris Email - Milk Analyzer Machine) Communication received on March 9, 2023 [Equipment \(mirissolutions.com\)](https://www.mirissolutions.com)

⁶ Quality and Safety. Prolacta Bioscience. Accessed on March 14, 2023. <https://www.prolacta.com/en/about-us/quality-and-safety/>

⁷ Average Milk Technician Salary for Washington State. ZipRecruiter. [Referenced on March 14, 2023. https://www.ziprecruiter.com/Salaries/What-Is-the-Average-Milk-Technician-Salary-by-State.](https://www.ziprecruiter.com/Salaries/What-Is-the-Average-Milk-Technician-Salary-by-State)

the department, record keeping, and verification of any required inspections, accreditation and permits.

Cost(s): The department estimates it will take 4 hours of administrative work at average salary of \$19 per hour⁸ for a milk bank employee’s time to complete the certification application and provide supporting documentation every 5 years. Therefore, the department anticipates the cost for certification to be \$76 every 5 years.

Benefit(s): Provides an enforcement mechanism for the department to ensure milk and milk bank safety.

Summary of all Cost(s) and Benefit(s)

SA Table 2. Summary of Section 5 probable cost(s) and benefit(s)

WAC Section and Title	Probable Cost(s)	Probable Benefit(s)
246-720-030 Screening Milk Donors	Indeterminate. If the most commonly spoken languages are requested, the department anticipates a one-time cost of \$3,015	The proposed rule ensures that information be provided to the milk donor in the language of their choice, allowing for ease of understanding and increased equity.
246-720-050 Milk Donor Education and Procedures	See above, 246-720-030 Screening Milk Donors	The proposed rule ensures that information be provided to the milk donor in the language of their choice, allowing for ease of understanding and increased equity.
246-720-070 Milk Bank Operating Standards	Estimated costs are negligible	Provides a mechanism for the department to ensure milk banks are meeting existing federal food safety standards.
246-720-080 Milk Processing	\$0. The department does not anticipate additional costs.	The changes in this section ensure that the department is not excluding milk banks that process human milk for use as human milk derived product since those processes may differ from

⁸ Based on U.S. Bureau of Labor Statistics mean hourly wage for medical secretaries and administrative assistants in May 2021. [Medical Secretaries and Administrative Assistants \(bls.gov\)](https://www.bls.gov)

		HMBANA standards. Including milk banks that process human milk for use as human milk derived produce is important to ensure that their products are safe for use with medically fragile infants in inpatient settings.
WAC 246-720-090 Additional requirements for donor human milk provided by compensated donors.	Indeterminate. Human milk analyzer equipment estimated at \$9,962 in the first year. Personnel time from a milk sampling technician would be needed, but number of hours are indeterminate.	Ensures that milk provided by compensated donors is unadulterated and safe for use.
WAC 246-720-100 Certification	\$76 every 5 years for administrative work	Provides an enforcement mechanism for the department to ensure milk and milk bank safety.

The probable benefits described in this analysis are qualitatively and quantitatively substantial and important to ensure the public health and safety of the state’s most medically fragile infants. Access to safe donor human milk and human milk derived products improves health outcomes for infants, including a reduced risk of infections and sudden infant death syndrome.

Since many milk banks are accredited by HMBANA and therefore meet most standards set in this rule, the probable costs for the majority of milk banks is estimated by the department to be minimal, see Table 2 above. However, milk banks who receive milk from compensated donors will have additional costs for testing to ensure milk is unadulterated. Possible testing options provided in the rule include using a milk analyzer or DNA testing, while allowing for other methods as well. The costs for such testing are indeterminate at this time.

Determination

Probable Benefits greater than Probable Costs

In conclusion, the department determined the probable benefits of the rule outweigh the probable costs.

SECTION 6

List of alternative versions of the rule that were considered including the reason why the proposed rule is the least burdensome alternative for those that are required to comply and that will achieve the goals and objectives of the proposed rule.

E2SSB 5702 requires the department to develop minimum standards to ensure milk bank safety for human milk and human milk derived products prescribed for inpatient use, specifically “*the standards adopted by the department, must, at a minimum, consider the clinical, evidence-based guidelines established by a national accrediting organization.*” HMBANA serves as the only professional organization that accredits nonprofit milk banks in the United States and Canada. HMBANA guidelines are considered the gold standard. Therefore, the department has incorporated many of the HMBANA standards into the rule.

Additional requirements for donor human milk provided by compensated donors. The department determined that additional testing for milk provided by compensated donors was necessary because there is a higher risk of adulteration given that it benefits compensated donors to donate in larger quantities. The department heard from milk banks who compensate donors that testing for adulteration was already a current practice in their facilities and asked that this testing be included in the rule.

Certification. This section allows the department to enforce the safety standards incorporated in rule. The department considered other, more robust, enforcement mechanisms such as licensure, but determined that these processes would be time-consuming and cost-prohibitive for milk banks.

More stringent testing. E2SSB 5702 also requires the department to “review and consider requiring additional testing standards, including but not limited to testing for the presence of viruses, bacteria, and prescription and nonprescription drugs.” Consequently, the department also considered including more stringent testing for infectious disease, medications, illegal substances, and nicotine. Department epidemiologists were consulted and it was determined that the rule was sufficient to prevent the transmission of diseases or substances in human milk. Furthermore, more stringent testing could be cost prohibitive for nonprofit milk bank operations. The department attempted to balance proven safety methods with ensuring access and therefore determined more stringent testing was unnecessary for inclusion.

SECTION 7

Determination that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The department has determined that the proposed rules do not require any action that violates or conflicts with any other state or federal law.

SECTION 8

Determination that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9

Determination if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The proposed rule does not differ from any applicable federal regulation or statute.

SECTION 10

Demonstration that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The federal Food and Drug Administration (FDA) considers donor human milk a food source rather than a medical product and does not have established standards for donor human milk. Donor human milk has not been regulated by the state. This rule is the first regulation set in Washington on the subject.

Human milk derived products are regulated as exempt infant formulas by the FDA. The department reviewed these regulations and determined that the proposed rule has been coordinated to the extent practicable.

To understand any impacts to other government agencies or the people they serve, and for the purpose of coordination with agencies who provide coverage for donor human milk and human milk derived products; the department informed the Health Care Authority and the Office of the Insurance Commissioner of this rulemaking.