

## WSR 23-08-054

## PROPOSED RULES

## DEPARTMENT OF HEALTH

[Filed April 2, 2023, 12:46 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 22-15-044.

Title of Rule and Other Identifying Information: Chapter 246-720 WAC, Human donor milk bank standards. The department of health (DOH) is proposing new standards for ensuring human milk bank safety.

Hearing Location(s): On May 16, 2023, at 1:30 p.m. DOH will be holding a virtual-only hearing. Register in advance for this webinar [https://us02web.zoom.us/webinar/register/WN\\_zBaU-LkLTGanSFTVyyQCuQ](https://us02web.zoom.us/webinar/register/WN_zBaU-LkLTGanSFTVyyQCuQ). After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: May 23, 2023.

Submit Written Comments to: Ashley Noble, P.O. Box 47380, Olympia, WA 98504-7380, email [donormilkbankrule@doh.wa.gov](mailto:donormilkbankrule@doh.wa.gov), <https://fortress.wa.gov/doh/policyreview/>, by May 16, 2023.

Assistance for Persons with Disabilities: Contact Ashley Noble, phone 360-628-3667, TTY 711, email [donormilkbankrule@doh.wa.gov](mailto:donormilkbankrule@doh.wa.gov), by May 2, 2023.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: E2SSB 5702 (chapter 236, Laws of 2022) 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 DOH to develop minimum standards to ensure milk bank safety for donor 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. To ensure the safety of donor human milk and human milk derived products, DOH is proposing rules to establish safety standards for donor screening, testing, milk handling and processing, and recordkeeping as required by the statute.

Reasons Supporting Proposal: E2SSB 5702 requires the department to adopt standards to ensure the safety of donor human milk and human milk derived products. Rules are necessary to create enforceable standards to ensure that donor human milk and human milk derived products 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.

Statutory Authority for Adoption: E2SSB 5702 (chapter 236, Laws of 2022).

Statute Being Implemented: E2SSB 5702 (chapter 236, Laws of 2022).

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: DOH, governmental.

Name of Agency Personnel Responsible for Drafting: Ashley Noble, 111 Israel Road S.E., Mailstop 47830, Tumwater, WA 98501, 360-628-3667; Implementation and Enforcement: Shevonne Tsegaye, 111 Israel Road S.E., Mailstop 47830, Tumwater, WA 98501, 564-669-4454.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Ashley Noble, P.O. Box 47380, Olympia, WA 98504-7380, phone 360-628-3667, TTY 711, email ashley.noble@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules are adopting or incorporating by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule.

Scope of exemption for rule proposal:

Is partially exempt.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated. DOH analyzed costs in the significant analysis and found that many of the costs (that were not exempted by alignment with national standards) were indeterminate, variable, or negligible. Of the costs that were known and analyzed by the department in the significant analysis, the costs of the proposed rule were found to be **less than** the minor cost thresholds (\$34,649.61 and \$64,775.78).

March 31, 2023  
Kristin Peterson, JD  
Chief of Policy  
for Umair A. Shah, MD, MPH  
Secretary

**OTS-4401.3**

**Chapter 246-720 WAC  
HUMAN DONOR MILK BANK STANDARDS**

NEW SECTION

**WAC 246-720-001 Purpose and applicability.** The purpose of this rule is to promote and establish consistent standards for milk banks that provide health care facilities and providers and International Board-Certified Lactation Consultants donated human milk or human milk derived products prescribed for inpatient use that will be billed to an insurance carrier. To qualify for certification a milk bank must comply with this chapter, RCW 41.05.017, chapters 43.70, 48.43, and 74.09 RCW, and any other state or federal requirements.

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NEW SECTION

**WAC 246-720-010 Definitions.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Adulterated" means the addition of a substance other than human milk to artificially increase the volume of a donation to a milk bank.

(2) "Compensation" means monetary or in-kind payment or donation to either a milk donor or a third party made in exchange for donated human milk.

(3) "Current good manufacturing practice" or "CGMP" means the regulations adopted by the United States Food and Drug Administration (FDA) under Title 21, Chapter 1, Subchapter B, Part 117 of the Code of Federal Regulations.

(4) "Department" means the Washington state department of health.

(5) "Donor human milk" means human milk that has been contributed to a milk bank by one or more donors.

(6) "Food safety plan" or "FSP" means a written plan to significantly minimize or prevent biological, chemical, and physical hazards in a milk bank.

(7) "Human milk derived product" means donor human milk which has been processed to alter or concentrate the nutrient composition including, but not limited to, human milk derived fortifiers.

(8) "Milk bank" means an organization that engages in the procurement, processing, storage, distribution, or use of human milk contributed by donors. This definition does not include hospitals that act as milk collection sites or distribute or use donor milk received from an offsite milk bank.

(9) "Milk depot" means a drop-off or collection site for donor milk that then gets transported to a milk bank.

(10) "Milk donor" means a lactating person who has passed a health screening and voluntarily donates milk.

(11) "Preventive controls qualified individual" or "PCQI" means a person who has completed a formal certification program through the Food Safety Preventive Controls Alliance (FSPCA).

(12) "Processing" means the use of evidence-based methodologies to prepare safe milk for recipients including, but not limited to, pasteurization.

(13) "Unit of alcohol" means a standard drink which contains 0.6 ounces (14.0 grams or 1.2 tablespoons) of pure alcohol.

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NEW SECTION

**WAC 246-720-020 Milk bank organizational structure.** A milk bank must, at a minimum, have:

(1) An executive director or milk bank coordinator to oversee business, clinical, and laboratory operations;

(2) A medical director who provides clinical guidance and policy review;

(3) Staff, including health care professionals, donor screeners, and lab technicians, who demonstrate:

- (a) Knowledge of food safety, food processing, PCQI training content, and applicable municipal, state, and federal regulations; and
- (b) Documented on-going education and training critical to the safe provision of donor human milk;
- (4) A board of directors and a medical advisory committee with a wide representation of relevant experience and skills.

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NEW SECTION

**WAC 246-720-030 Screening milk donors.** A milk bank must screen a milk donor consistent with the requirements of this section in order to register with the department.

(1) A milk bank must screen a milk donor prior to their first milk donation including, but not limited to:

(a) A donor must be screened verbally as well as in writing and provided educational materials. Screenings must be conducted in the language in which the donor is most comfortable communicating whenever possible. Educational materials provided to milk donors must also be written in the language of the milk donor's choice.

(b) A milk bank must serologically screen a potential milk donor for human immunodeficiency virus (HIV)-1 and -2, human T-lymphotropic virus (HTLV)-1 and -2, hepatitis C, hepatitis B, and syphilis.

(c) As part of the screening process, a milk bank must instruct a milk donor about situations in which they must temporarily or permanently discontinue donation and report such situations to the milk bank.

(2) A milk bank must prohibit a milk donor from donating milk temporarily or permanently if any of the following situations apply. The milk donor:

(a) Consumes any product that contains tobacco or nicotine within 30 days of milk donation;

(b) Consumes any product that contains cannabis or cannabidiol (CBD) at any time if they wish to donate milk;

(c) Consumes recreational drugs at any time if they wish to donate milk;

(d) Is at risk of developing Creutzfeldt-Jakob disease (CJD) or must defer travel related to CJD risk. A person who is at risk of developing CJD is not eligible to donate milk under this chapter;

(e) Receives a positive serological test result for HIV-1 or -2, HTLV-1 or -2, hepatitis B or C, or syphilis. The milk donor may donate milk after receiving a negative serological test for any of these viruses;

(f) Uses medications which are determined by a medical advisory council or a medical director qualified in pharmacology to be contraindicated during lactation;

(g) Has received a blood transfusion within the last 90 days;

(h) Is at risk for contracting a bloodborne illness;

(i) Has received body piercings, tattoos, or permanent makeup within the last 90 days;

(j) Has undergone an organ or tissue transplant within the past 90 days. If the donor is receiving immunosuppressive therapy, a medical advisory board or medical director must determine if the donor is eligible to donate milk;

(k) Practices a vegan diet and does not supplement their diet with vitamin B-12 (cobalamin);

(1) Has consumed one unit of alcohol within six hours (360 minutes) of milk expression for donation. If a milk donor has consumed two units of alcohol, then the donor must wait a total of 12 hours (720 minutes) prior to milk expression for donation. Daily alcohol intake may require permanent suspension of milk donation to ensure donor milk safety.

(3) A milk bank must communicate with each milk donor at least every two months during the donation period to update changes in the donor's health, medical status, medications, tobacco use, and recreational drug use.

(4) All information pertaining to donor screening, including written and verbal communication with donors, comply with the Washington state's Uniform Health Care Information Act (chapter 70.02 RCW) and applicable federal health care information privacy laws.

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#### NEW SECTION

**WAC 246-720-040 Milk handling restrictions.** A milk bank must meet the following milk handling restrictions in order to register with the department:

(1) Milk may not be donated if it has been heat-treated in any way by the milk donor.

(2) Milk may be temporarily stored by a milk donor in the refrigerator for a maximum of 96 hours before being moved to the freezer for long-term storage.

(3) Milk that has been frozen for storage purposes expires one year from the date of expression and may not be donated.

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#### NEW SECTION

**WAC 246-720-050 Milk donor education and procedures.** (1) A milk bank must instruct a milk donor both verbally and in writing in a language of the donor's choice about:

(a) Potential risks such as medication, dietary supplement, and herbal supplement use, illnesses, and recreational drug use;

(b) The potential that the milk bank may require a milk donor to defer or cease donation in the event the milk bank identifies risks related to the milk donor;

(c) Appropriate methods for clean expression, handling, storage, and transportation of human milk; and

(d) Contacting the milk bank to report household illnesses and any changes in the milk donor's health status or medication use.

(2) A milk bank must provide a milk donor with written instructions, in a language of the donor's choice, containing, at a minimum:

(a) Clean technique for milk collection, including, at a minimum:

(i) Hand washing;

(ii) Washing pump parts and containers;

- (iii) Appropriate containers for storing donor milk; and
- (iv) Handling of milk containers, both while storing milk and during transit to the milk bank.
- (b) When a milk donor should refrain from donating and circumstances that may affect their eligibility as a donor.
- (c) Labeling of donated milk including, but not limited to, donor identification and date of collection.
- (d) Optimal procedure for freezing and storage of milk.
- (e) How to transport milk safely to the milk bank or depot.
- (3) A milk bank must provide a milk donor with the following written information to ensure that donors are fully informed of their rights and responsibilities in the language of the donor's choice:
  - (a) A statement regarding confidentiality of records;
  - (b) A statement that approval as a milk donor does not indicate that a donor's milk is safe to share or sell informally;
  - (c) An explanation of the required serology tests and what actions are taken when positive tests are received, according to a plan developed by each milk bank, and in accordance with state or federal regulations.

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#### NEW SECTION

**WAC 246-720-060 Milk bank standard operating procedures.** A milk bank must maintain detailed standard operating procedures that are available to all staff. Standard operating procedures must be updated annually. Standard operating procedures must include, at a minimum, procedures addressing the following:

- (1) Donor screening and serological testing;
- (2) Pasteurization or thermal processing;
- (3) Microbiological testing;
- (4) Receiving, storage, and transport of donor milk;
- (5) Sanitation and cGMPs;
- (6) Emergency preparedness;
- (7) Recall.

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#### NEW SECTION

**WAC 246-720-070 Milk bank minimum operating standards.** A milk bank must meet the following minimum operating standards to register with the department:

- (1) A milk processing facility must be suitable in size, construction, and design to ensure sanitary operations for milk processing activities and comply with all United States Food and Drug Administration food manufacturing safety requirements for food manufacturing facilities.
- (2) Equipment intended for milk processing must be used only for milk banking purposes or processing of human milk-derived products.
- (3) Equipment must be cleaned and maintained according to manufacturer's instructions.

(4) Equipment and utensils must be designed and made from noncorrosive food grade material that can be adequately cleaned and maintained. The design, construction, and use of equipment and utensils must not result in contamination of milk.

(5) Freezers must be locked or located in a secured area and inaccessible to the public.

(6) Freezer temperatures must be maintained at  $-18^{\circ}\text{C}$  ( $0^{\circ}\text{F}$ ) or less.

(7) Refrigerator temperatures must be maintained between  $1^{\circ}\text{C}$  and  $4^{\circ}\text{C}$  ( $40^{\circ}\text{F}$ ).

(8) Commercial dish washing machines must reach a minimum boost temperature of  $82.2^{\circ}\text{C}$  ( $180^{\circ}\text{F}$ ) with every cycle.

(9) Dish washing machine sanitizers and rinse agents must be food safe and appropriate for the make and model of the dish washing machine.

(10) Thermometers must be calibrated to a National Institute of Standards and Technology (NIST) reference thermometer each quarter, or more often if dropped, damaged, or any time a thermometer's accuracy is in question.

(11) Each milk bank must have a quality assurance program that includes, at a minimum:

(a) cGMP program monitoring and recordkeeping, including:

(i) Sanitation and pest control schedules and checklists;

(ii) Staff education and training records;

(iii) Equipment maintenance and calibration schedules and records.

(b) Verification and validation activities, including:

(i) Dish washing machine temperature verification;

(ii) Sanitizer and disinfectant chemical concentration verification;

(iii) Milk donor and batch record self-audits to validate critical limits are met.

(c) Records of safety meetings and root cause analyses.

(d) Mock donor human milk recalls.

(e) Annual standard operating procedure and FSP review and revision. An FSP must include a hazard analysis, preventive controls, monitoring actions, corrective actions, verifications and validations, supply chain management programs, a recall plan, and records of actions to support the food safety plan.

(12) A milk bank must comply with the Food Safety Modernization Act (FSMA) and register with the FDA as a food manufacturer biannually. Milk banks must maintain records of passing FDA inspections and provide those records to the department upon request.

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#### NEW SECTION

**WAC 246-720-080 Milk processing.** A milk bank must meet the following milk processing criteria in order to register with the department:

(1) A milk bank must use an electronic inventory system to account for every ounce of donated human milk received, processed, dispensed, discarded, or used for research.

(2) Donated human milk must be traceable to a specific milk donor throughout every step in the collection and donation process.

(3) A milk bank must maintain detailed logistics records, related to donated human milk including, but not limited to, incoming shipping records, receiving date, volume, and the condition of the donated human milk.

(4) Frozen donated human milk must be gradually thawed in a manner that prevents contamination, with careful monitoring and record-keeping documenting adherence to time and temperature requirements.

(5) Donated human milk from multiple donors may be pooled together to create a uniform batch of donor milk. Pooling must be performed with aseptic technique under clean conditions and must be adequately mixed to ensure an even macronutrient distribution throughout the batch.

(6) Donated human milk must be strained with a food grade filter before bottling.

(7) Processed donated human milk must be stored in FDA-approved glass or food-grade plastic containers. Containers must be airtight and leakproof.

(8) Stored donated human milk must be thermally processed, which includes, but is not limited to, pasteurization, prior to storage. Following thermal processing, milk must be rapidly chilled using either processing equipment manufactured to cool milk or ice baths. Human milk-derived products must be thermally processed in accordance with FDA regulations under the pasteurized milk ordinance (PMO), FDA Title 21 Code of Federal Regulations (C.F.R.) Subchapter B-Foods for Human Consumption Parts 100-169.

(9) Each batch of processed donated human milk or human milk-derived products must be cultured for bacteria. Post-pasteurization or thermal processing, bacteriological testing must be conducted by a third-party accredited lab. Clinical labs must maintain Clinical Laboratory Improvement Amendments (CLIA) or equivalent certification. Food testing labs must meet International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. Donated human milk or human milk-derived products that fail bacteriological testing must not be dispensed.

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#### NEW SECTION

**WAC 246-720-090 Additional requirements for donor human milk provided by compensated donors.** A milk bank that obtains donor human milk from donors who are compensated must also test the donor human milk to ensure that it is unadulterated and contains only human milk.

(1) To ensure donor human milk is unadulterated a milk bank may use methods including, but not limited to, a milk analyzer or DNA testing.

(2) If a milk bank finds donated human milk to be adulterated or to contain milk not from the milk donor, the milk bank must discard the donated human milk.

(3) If a milk bank finds more than once that donated human milk from a milk donor is adulterated or contains milk not from the screened milk donor, the milk bank must suspend the milk donor from participation in milk donation.



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NEW SECTION

**WAC 246-720-100 Certification.** (1) The department may issue a certification to a milk bank that demonstrates to the satisfaction of the department that it meets the standards under this chapter.

(2) Certifications are valid for five years and may be renewed with the department upon expiration.

(3) To apply for certification, a milk bank must submit to the department an application on forms provided by the department.

(4) The department may deny or revoke a certification for failure to meet minimum standards under this chapter.

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