

WSR 23-17-149

PERMANENT RULES

DEPARTMENT OF HEALTH

[Filed August 22, 2023, 12:15 p.m., effective September 22, 2023]

Effective Date of Rule: Thirty-one days after filing.

Purpose: E2SSB 5702 (chapter 236, Laws of 2022) requires the department of health (department) 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, the department is adopting safety standards in chapter 246-720 WAC to include donor screening and testing, milk handling and processing, and recordkeeping as required by the statute.

Citation of Rules Affected by this Order: New WAC 246-720-001, 246-720-010, 246-720-020, 246-720-030, 246-720-040, 246-720-050, 246-720-060, 246-720-070, 246-720-080, 246-720-090, and 246-720-100.

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

Adopted under notice filed as WSR 23-08-054 on April 2, 2023.

Changes Other than Editing from Proposed to Adopted Version: (1) WAC 246-720-010(8) includes "milk depots" in the exclusion of the definition of "milk bank."

(2) WAC 246-720-030 (1)(a) allows for donors to be screened verbally or in writing.

(3) WAC 246-720-030 (2)(i), the donation deferral period is clarified to align with current HMBANA standards, as six months only if the procedure used nonsterile needles, equipment, or dyes.

(4) WAC 246-720-050(1) allows donors to be provided instruction verbally or in writing.

(5) WAC 246-720-060 is changed to require standard operating procedures be updated every two years rather than annually.

(6) WAC 246-720-070(3) clarifies equipment can be cleaned in a method other than the manufacturer's recommendation when validated as appropriate by the Food and Drug Administration (FDA).

(7) WAC 246-720-080(8) is changed to remove language citing FDA regulations. To comply with this rule, per WAC 246-720-001, purpose milk banks already must comply with relevant federal requirements; therefore, the citation is unnecessary.

A final cost-benefit analysis is available by contacting Hannah Febach, P.O. Box 47830, Olympia, WA 98504-7830, phone 360-485-5269, TTY 711, email Hannah.Febach@doh.wa.gov.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 11, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 11, Amended 0, Repealed 0.

Date Adopted: August 22, 2023.

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

OTS-4401.4

**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.

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 con-

tributed by donors. This definition does not include hospitals that act as milk collection sites or milk depots, or that procure, store, 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.

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.

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 or 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 undergone any procedure within the last six months using nonsterile needles, equipment, or dyes (e.g., piercings, tattoos, acupuncture, permanent makeup, microblading, or microneedling);

(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);

(l) 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.

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.

NEW SECTION

WAC 246-720-050 Milk donor education and procedures. (1) A milk bank must instruct a milk donor verbally or 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.

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 every two years. 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.

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 or in a method other than the manufacturer's recommendation only when otherwise validated as appropriate by the FDA.
- (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°C (0°F) or less.
- (7) Refrigerator temperatures must be maintained between 1°C and 4°C (40°F).
- (8) Commercial dish washing machines must reach a minimum boost temperature of 82.2°C (180°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.

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.
- (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.

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.

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.