



# PROPOSED RULE MAKING

**CR-102 (July 2022)**  
**(Implements RCW 34.05.320)**  
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: April 02, 2023

TIME: 12:46 PM

WSR 23-08-054

Agency: Department of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 22-15-044; or

Expedited Rule Making--Proposed notice was filed as WSR \_\_\_\_; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW \_\_\_\_.

Title of rule and other identifying information: Chapter 246-720 WAC, donor human milk bank standards. The Department of Health is proposing new standards for ensuring human milk bank safety.

### Hearing location(s):

Date: Time: Location: (be specific) Comment:

Date:	Time:	Location: (be specific)	Comment:
May 16, 2023	1:30 PM	The Department of Health will be holding a virtual only hearing.  Register in advance for this webinar: <a href="https://us02web.zoom.us/webinar/register/WN_zBaU-LkLTGanSFTVyyQCuQ">https://us02web.zoom.us/webinar/register/WN_zBaU-LkLTGanSFTVyyQCuQ</a>  After registering, you will receive a confirmation email containing information about joining the webinar.	

Date of intended adoption: May 23, 2023 (Note: This is **NOT** the effective date)

### Submit written comments to:

Name: Ashley Noble  
Address: PO Box 47380 Olympia, WA 98504-7380  
Email: donormilkbankrule@doh.wa.gov  
Fax: N/A  
Other: <https://fortress.wa.gov/doh/policyreview/>  
By (date) May 16, 2023

### Assistance for persons with disabilities:

Contact: Ashley Noble  
Phone: 360-628-3667  
Fax: N/A  
TTY: 711  
Email: donormilkbankrule@doh.wa.gov  
Other:  
By (date) May 2, 2023

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** Engrossed Second Substitute Senate Bill (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 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

proposing rules to establish safety standards for donor screening, testing, milk handling and processing, and record keeping 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:** Engrossed Second Substitute Senate Bill 5702 (chapter 236, Laws of 2022)

**Statute being implemented:** Engrossed Second Substitute Senate Bill 5702 (chapter 236, Laws of 2022)

**Is rule necessary because of a:**

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

**Type of proponent:**  Private  Public  Governmental

**Name of proponent:** (person or organization) Department of Health

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting: Ashley Noble	111 Israel Rd S.E. MS 47830, Tumwater, WA 98501	360-628-3667
Implementation: Shevonne Tsegaye	111 Israel Rd S.E. MS 47830, Tumwater, WA 98501	564-669-4454
Enforcement: Shevonne Tsegaye	111 Israel Rd S.E. MS 47830, Tumwater, WA 98501	564-669-4454

**Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?**

Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

**Is a cost-benefit analysis required under [RCW 34.05.328](#)?**

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Ashley Noble

Address: PO Box 47380 Olympia, WA 98504-7380

Phone: 360-628-3667

Fax:

TTY: 711

Email: ashley.noble@doh.wa.gov

Other:

No: Please explain:

**Regulatory Fairness Act and Small Business Economic Impact Statement**

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

**(1) Identification of exemptions:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

[RCW 34.05.310](#) (4)(b)  
(Internal government operations)

[RCW 34.05.310](#) (4)(e)  
(Dictated by statute)

[RCW 34.05.310](#) (4)(c)  
(Incorporation by reference)

[RCW 34.05.310](#) (4)(f)  
(Set or adjust fees)

[RCW 34.05.310](#) (4)(d)  
(Correct or clarify language)

[RCW 34.05.310](#) (4)(g)  
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW \_\_\_\_\_.

Explanation of how the above exemption(s) applies to the proposed rule:

**(2) Scope of exemptions:** *Check one.*

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

**(3) Small business economic impact statement:** *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The department 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).

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name: Ashley Noble  
Address: PO Box 47380 Olympia, WA 98504-7380  
Phone: 360-628-3667  
Fax:  
TTY: 711  
Email: [ashley.noble@doh.wa.gov](mailto:ashley.noble@doh.wa.gov)  
Other:

**Date:** 3/31/2023

**Name:** Kristin Peterson, JD for Umair A. Shah, MD, MPH

**Title:** Chief of Policy for Secretary of Health

**Signature:**

