



PREPROPOSAL STATEMENT OF INQUIRY

**CR-101 (October 2017)
(Implements RCW 34.05.310)**

Do **NOT** use for expedited rule making

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DATE: July 15, 2022

TIME: 10:58 PM

WSR 22-15-044

Agency: Department of Health

Subject of possible rule making: Chapter 246-720 WAC, donor human milk bank standards. The Department of Health is considering adopting new standards for ensuring human milk bank safety.

Statutes authorizing the agency to adopt rules on this subject: Engrossed Second Substitute Senate Bill 5702 (chapter 236, Laws of 2022)

Reasons why rules on this subject may be needed and what they might accomplish: E2SSB 5702 requires the Department of Health (department) to adopt standards to help ensure the safety of human milk donated to milk banks. Beginning January 1, 2023 health carriers shall provide coverage for medically necessary donor human milk for inpatient use when ordered by a licenses health care provider with prescriptive authority or an international board certified lactation consultant. The statute sets specific criteria for coverage.

To ensure the safety of the donated milk rules may need to be established to address proper screening, milk handling and processing, and recordkeeping. The department will also consider testing standards for the presence of viruses, bacteria, and prescription and nonprescription drugs in the donated milk.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: Donor human milk banks are not regulated by Washington State or federal agencies at this time.

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative rule making.


Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

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Additional comments: To be added to the Department of Health's interested parties list please contact Michelle Izumizaki or Ashley Noble.

Date: 07/07/2022	Signature: 
Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH	
Title: Deputy Secretary for Policy and Planning for Secretary of Health	