



PROPOSED RULE MAKING

CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 03, 2021

TIME: 10:28 AM

WSR 21-10-077

Agency: State Board of Health

Original Notice

Supplemental Notice to WSR 20-24-119

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 18-24-016 ; 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).

Proposal is exempt under RCW .

Title of rule and other identifying information: (describe subject) Chapter 246-680 -Prenatal Tests - Congenital and Heritable Disorders. The State Board of Health (Board) is filing a supplemental notice to WSR 20-24-119 proposing additional amendments to rules to align the prenatal screening and diagnostic tests that are considered medically necessary and required to be included in benefits packages by certain payers with national standards of care and current best practices.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
06/09/2021	1:30 PM	<p>In response to the coronavirus disease 2019 (COVID-19) public health emergency, the State Board of Health will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical space, will be held instead. Board member, presenters, and staff will all participate remotely. The public may login using a computer or device, or call-in using a phone to listen to the meeting through the Go To Webinar application. The public may submit verbal comments during the specified rules hearing segment.</p> <p>To access the meeting online and register: https://attendee.gotowebinar.com/register/340060668939096335</p> <p>You can also dial-in and listen/observe only using your phone: Call: +1 (914) 614-3221 Access Code: 175-500-000</p>	

--	--	--	--

Date of intended adoption: 06/09/2021 (Note: This is **NOT** the **effective** date)

Submit written comments to:
 Name: Samantha Pskowski
 Address: PO Box 47990
 Olympia, WA 98504-7990
 Email: <https://fortress.wa.gov/doh/policyreview>
 Fax: N/A
 Other: None
 By (date) 05/26/2021

Assistance for persons with disabilities:
 Contact Samantha Pskowski
 Phone: (360) 789-2358
 Fax:
 TTY: 711
 Email: samantha.pskowski@sboh.wa.gov
 Other:
 By (date) 06/02/2021

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this proposal is to update the Board's existing rules outlining prenatal screenings and diagnostic tests required to be covered by certain payers to align with current clinical standards and best practices. The Board's rule was last updated in 2003, and since such time, new screenings and diagnostics have become available and standards of practice have been revised. This proposal would increase access to certain prenatal screening and diagnostic testing for pregnant individuals.

The Board held a public hearing on January 13, 2021. The Board determined it would continue its consideration of the proposal until its June 9, 2021 meeting in recognition of interested parties' significant comment regarding certain prenatal tests and requirements for pre- and post-procedure genetic counseling. As a result of public comments, the Board has made the following changes to the proposed rule since it was filed in December 2020 as WSR 20-24-119: requirements for documentation of genetic counseling for cell-free DNA testing, clarification that cytogenomic microarray testing should be targeted, clarification that certain tests do not require pre- and post-procedure genetic counseling, and other administrative changes.

Reasons supporting proposal: There have been many advances in prenatal screening over the years. These newer procedures offer better detection rates for birth defects or genetic conditions, as well as lower false positive rates. The purpose of the proposed rule is to continue to ensure equity for accessing prenatal screening and diagnostic services for pregnant individuals that choose them and to bring the rule into alignment with national standards of care and current best practices.

In 1988, the Washington State Legislature passed legislation that: (1) required healthcare providers treating pregnant individuals to inform them about the availability of prenatal screening and testing options (RCW 70.54.220); (2) required multiple payers to cover such services (RCW 48.21.244, RCW 48.44.344 and RCW 48.46.375); and (3) placed limitations on certain payers to ensure they did not cancel, reduce, or alter coverage provided solely based on results of a prenatal test (RCW 48.42.90). The Board has the authority to establish standards in rule for screening and diagnostic procedures during pregnancy when those services are determined to be medically necessary. The regulations were written to eliminate the coercive and unethical practices of some payers who offered to cover the costs of prenatal screening and diagnostic procedures only if patients signed an agreement that they would terminate the pregnancy if an abnormality was found.

All pregnancies have a 3-5% risk for a birth defect and may be at an additional risk for genetic disorders. Prenatal tests are available to provide information about some of these risks and can help improve health outcomes. Prenatal screening and diagnostic testing can have a significant impact on pregnancies at risk for a genetic condition or birth defect by: (1) Enabling early diagnosis or preventative approaches to reduce the amount of resources needed for postnatal diagnosis of symptomatic children; (2) Providing an opportunity to initiate appropriate health care services and interventions as soon as possible to improve the health of children and their families; and (3) Informing pregnant individuals and their families about health risks to current and future pregnancies to empower them to make informed pregnancy related health decisions.

Statutory authority for adoption: Statutory authority for adoption: RCW 43.20.050, RCW 48.21.244, RCW 48.44.344, RCW 48.46.375, and RCW 70.54.220

Statute being implemented: RCW 70.54.220, RCW 43.20.050, RCW 48.44.344, RCW 48.21.244, and RCW 48.46.375

Is rule necessary because of a:

Federal Law? Yes No
Federal Court Decision? Yes No
State Court Decision? Yes No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Washington State Board of Health Private
 Public
 Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358
Implementation:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358
Enforcement:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358

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: Samantha Pskowski

Address: PO Box 47990
Olympia, WA 98504-7990

Phone: (360) 789-2358

Fax: N/A

TTY: 711

Email: samantha.pskowski@sboh.wa.gov

Other:

No: Please explain:

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). 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).

Explanation of exemptions, if necessary: It has been determined that there are no small businesses in the Direct Health and Medical Insurance Carriers industry and therefore this proposal is exempt.

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If 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 analysis showing how costs were calculated.

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

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

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

Date: 05/03/2021

Signature:

Name: Michelle A. Davis



Title: Executive Director