Chapter 246-680 WAC

Prenatal Tests - Congenital and Heritable Conditions

January 13, 2021

Rule Background

- The Board has authority under RCW 48.21.244, 48.44.344, and 48.46.37 5 to establish standards for screening and diagnostic procedures for prenatal diagnosis of congenital disorders of the fetus
- The Board has authority under RCW 70.54.220 to establish criteria and timelines regarding the availability and use of prenatal tests for health care providers to share with pregnant women and couples
- The Board last updated the rule in 2003

Rulemaking Timeline

- The Department of Health made a request to the Board for rulemaking in 2014 which was denied at the time due to staff capacity and outstanding questions around genetic screening. In June 2018, the request was brought again to the Health Promotion Committee and recommended to be brought to the full Board.
- The Board received a presentation from the Department of Health and voted to direct staff to file a CR-101 to evaluate the request and consider possible rulemaking.
- Board and Department staff engaged stakeholders and distributed a draft for informal comment in June 2019.
- Staff worked to incorporate feedback and develop the rule analysis. Work was delayed due to staff vacancies.
- A CR-102 was filed on December 2, 2020, commencing the public comment period, which ended January 6, 2021.

Timeline

June 2018	November 2018	June 2019	November 2020	December 2020	January 2021
Dept. of Health requested rulemaking	CR-101 Filed	Informal draft distributed for comment	Board briefing on proposed rule	Filed CR-102; Public comment period through January 6th	Rules hearing

Proposed Changes

- Proposed rule changes update two sections:
    - WAC 246-680-010; Definitions
    - WAC 246-680-020; Board of health standards for screening and diagnostic tests during pregnancy

WAC 246-680-010; Definitions

- The proposed rule amends existing definitions, newly defines terms incorporated within existing terms, and eliminates certain terms;

Amended terms:

- Prenatal test
- Prenatal ultrasonography
- Preprocedure genetic counseling
- Postprocedure genetic counseling

Eliminated terms:

- Department
- Health care providers
- Prenatal carrier testing
- Qualified genetic counselor

Newly defined terms:

- Amniocentesis
- Carrier screening
- Chorionic villus sampling
- Maternal hepatitis B surface antigen (HBsAg) screening
- Maternal serum marker screening
- Percutaneous umbilical blood sampling
- Prenatal cell free DNA screening

WAC 246-680-010; Definitions (continued)

Amended terms:

- **Preprocedure genetic counseling:** "means a individual counseling that may be part of another procedure or service, involving a health care provider and a pregnant woman with or without family members to assess and identify increased risks for congenital abnormalities or pregnancy complications, offer specific carrier screening or diagnostic tests, discuss the purposes, risk, accuracy, and limitations of a prenatal testing procedure, aid in decision making and to assist in obtaining the desired testing or procedure."
- **Postprocedure genetic counseling**: "means individual counseling that may be part of another procedure or service involving a health care provider and a pregnant woman with or without other family members to discuss the results of the prenatal tests done, any further testing or procedures available or referrals for further consultation or counseling."

WAC 246-680-020; Board of health standards for screening and diagnostic tests during pregnancy

- This section outlines the standards of medical necessity for insurers, health care service contractors, and health maintenance organizations to use when authorizing requests or claims for prenatal screening or diagnosis

- Changes reflect updated standards of practice, including eliminating or revising restrictions for certain tests and adding new tests

WAC 246-680-020; Board of health standards for screening and diagnostic tests during pregnancy (continued)

- New Tests
  - Cytogenomic microarray analysis (CMA)
  - Chromosome analysis
  - Carrier screening
    - For recessive X-linked conditions if indicated by positive family history
    - For a defined list of conditions regardless of family history
  - Prenatal cell free DNA testing (cfDNA)
  - Molecular genetic or cytogenetic testing of parents

WAC 246-680-020; Board of health standards for screening and diagnostic tests during pregnancy (continued)

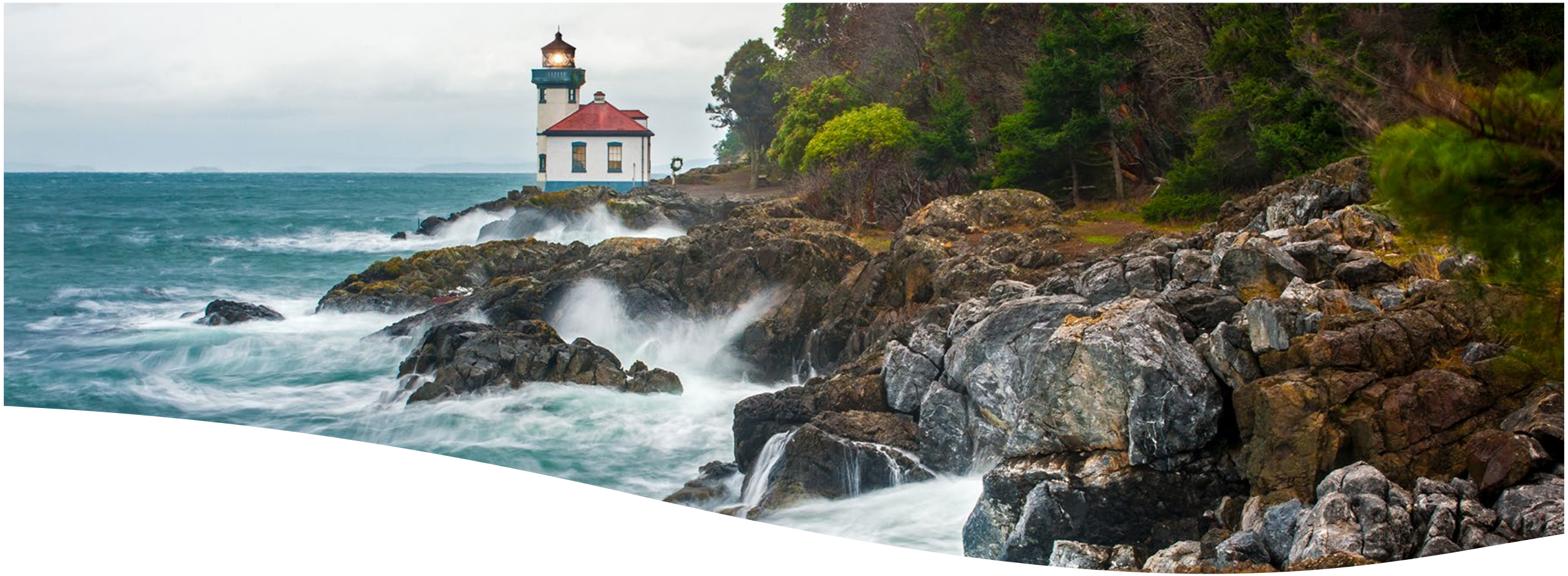
- Testing amended for the following tests:
    - Amniocentesis
    - Prenatal ultrasonography
    - Chorionic villus sampling
    - Fetal diagnostic testing

Comments Received

- Received two comments
- Two comments were received in support of the proposed rule
- Health Care Authority expressed concern about the potential cost of adding certain new tests.

Staff Recommendation:

- Continue discussions with interested parties to address concerns raised.
- File a supplemental CR-102 that reflects language changes to address concerns raised



Rules Hearing

Questions?

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THANK YOU

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