



# Chapter 246-680 WAC

Prenatal Tests - Congenital and Heritable Conditions

June 9, 2021



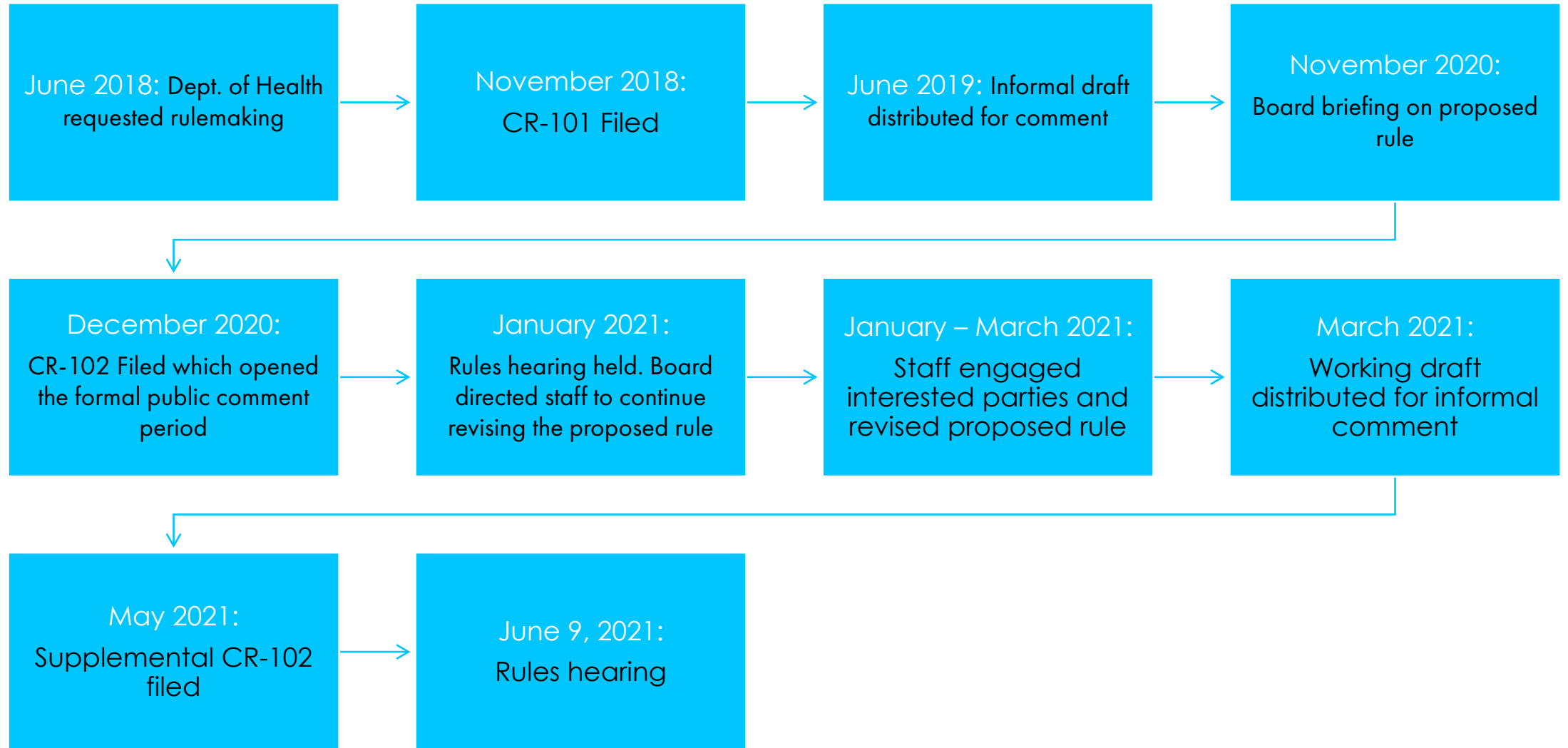
# Rule Background

- The Board has authority under RCW [48.21.244](#), [48.44.344](#), and [48.46.375](#) 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.
- A CR-102 was filed on December 2, 2020, commencing the public comment period, which ended January 6, 2021. A rules hearing was held on January 13, 2021.
- The Board directed staff to continue working with subject matter experts and interested parties to clarify rule language and return in June. Staff distributed a revised draft for informal comment in March 2021 and a supplemental CR-102 was filed on May 3, 2021.

# Timeline



# 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 246-680-020; 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
- Updates were made to reflect updated standards of practice, including eliminating or revising restrictions for certain tests and 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)

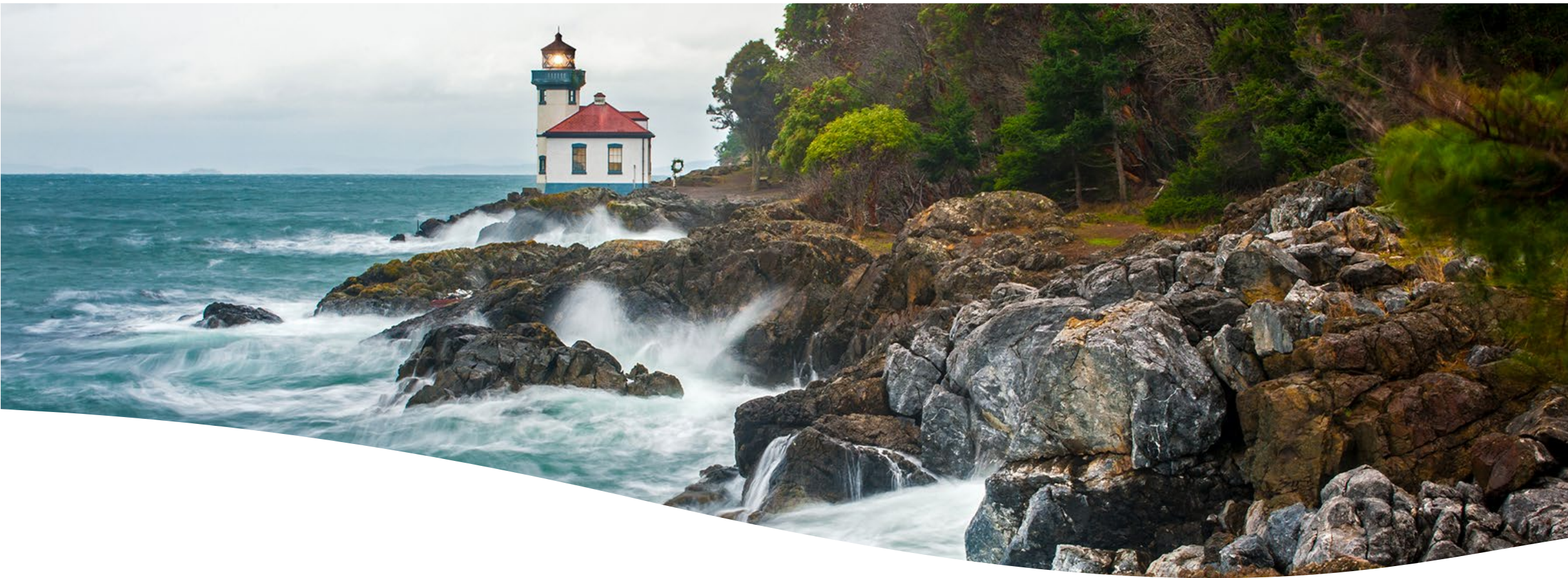
- Testing amended for the following tests:
  - Amniocentesis
  - Prenatal ultrasonography
  - Chorionic villus sampling
  - Fetal diagnostic testing

# Comments Received

- Received 2 comments
- One comment did not support genetic testing
- One comment suggested the Board consider review and revision of this rule on a more regular cadence, annual or biennial.

# Staff Recommendations

- Amend WAC 246-680-020(2)(g)(ii) requirements for cell-free DNA testing to address access barriers
  - (ii) There is documentation of ~~a scheduled appointment for how~~ postprocedure genetic counseling ~~will be provided~~; and



# Rules Hearing



# Questions?



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