Chapter 246-680 WAC

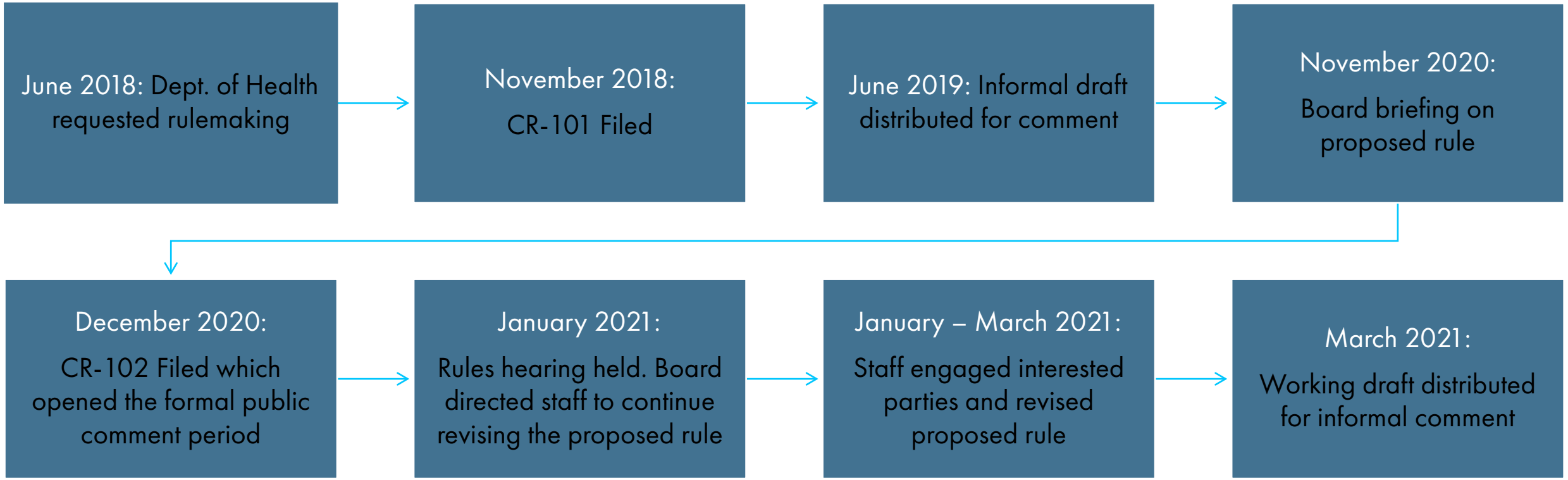
Prenatal Tests - Congenital and Heritable Conditions

April 14, 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.

Timeline


June 2018: Dept. of Health requested rulemaking
November 2018: CR-101 Filed
June 2019: Informal draft distributed for comment
November 2020: Board briefing on proposed rule
December 2020: CR-102 Filed which opened the formal public comment period
January 2021: Rules hearing held. Board directed staff to continue revising the proposed rule
January – March 2021: Staff engaged interested parties and revised proposed rule
March 2021: Working draft distributed for informal comment

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 subsequently 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. A rules hearing was held on January 13, 2021.
- The Board directed staff to clarify tests and requirements for counseling and bring this item back at the June 2021 meeting.

Recent Activities

- Following the January Board meeting, staff compiled and reviewed comment and worked to revise the draft as directed.
- A working draft was distributed for informal comment to interested parties and comments were collected in March 2021.
- Staff reviewed comments submitted and are working to revise the draft and update the accompanying analyses.
- Staff anticipate filing a new CR-102 in early May in anticipation of the June rules hearing.

Recap: Proposed Draft - December 2020

- Proposed rule changes updated two sections, WAC 246-680-010 and WAC 246-680-020.
- Changes to WAC 246-680-010 – Definitions, included removing specific requirements from the definition and clarifying the language for ease of use.
- Changes to WAC 246-680-020 - Board of health standards for screening and diagnostic tests during pregnancy, included:
    - Amendment to timing requirements for certain tests
    - Removal of restrictive criteria for certain tests and procedures to align with current standards of practice
    - Inclusion of new tests and procedures based on evidence of utility in the pregnant population

Working Draft – March 2021

- Adjusted criteria for certain tests:
    - Cell-free DNA testing/non-invasive pre-natal testing
        - Documentation of pre-procedure counseling
        - Documentation of a scheduled appointment for post-procedure counseling
    - Cytogenomic microarray analysis
        - For any woman undergoing amniocentesis or chorionic villus sampling
        - For instances of intrauterine fetal demise
        - On a case-by-case basis when medically indicated because of an abnormal ultrasound finding
- Replace “woman” with “person”.
- Clarify that certain tests do not require pre- and post-procedure genetic counseling.

Comments Received

- Received twelve comments.
- Comments received were specific to certain tests:
    - Carrier screening
    - Cell-free DNA testing
    - Chromosomal microarray
    - Molecular genetic or cytogenetic testing of parents
    - Pre- and post-procedure genetic counseling

Staff Recommendations

- Staff recommend adjusting requirements for certain tests:
  - Cell-free DNA testing/non-invasive pre-natal testing
    - Clarifies testing not covered for the sole purpose of determining sex of the fetus
  - Cytogenomic microarray analysis
    - For any person undergoing amniocentesis or chorionic villus sampling
    - For instances of recurrent intrauterine fetal demise

Next steps

- File a new CR-102 in early May
- Rules hearing at the Board's June 9, 2021 meeting

Questions?

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THANK YOU

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