

Date: April 14, 2021

To: Washington State Board of Health Members

From: Dr. Bob Lutz, MD, MPH, Board Member

Subject: Chapter 246-680 WAC, Prenatal Tests – Congenital and Hereditary Disorders

Background and Summary:

RCW 48.21.244, RCW 48.44.344, and RCW 48.46.375 state that certain insurers, health care service contractors, and health maintenance organizations which offer coverage for hospital, medical, or surgical expenses and provides benefits for pregnancy, childbirth, or related medical conditions must cover benefits for medically necessary prenatal diagnosis of congenital disorders by screening and diagnostic procedures in accordance with standards established by the Board. Chapter 246-680 WAC establishes these standards in determining medical necessity for screening and diagnostic procedures for diagnosis of congenital disorders of a fetus.

The State Board of Health (Board) last updated chapter 246-680 WAC in 2003. Since then there have been advances in medical science and additional evidence regarding prenatal tests is available. The Board filed a CR-101, Preproposal Statement of Inquiry, in November 2018. Staff from the Board and Department of Health (Department) engaged with stakeholders and distributed a draft for informal comment in June 2019. The CR-102, Proposed Rule was filed on December 2, 2020 as WSR 20-24-119 and a rules hearing was held on January 13, 2021.

The proposal would update the standards established by the Board for benefits to include all those that meet current standards of practice and are medically indicated. The proposed rule removes restrictive criteria for certain tests, includes new tests, and makes editorial changes to improve the usability of the rule. Recommendations for standards of care published by organizations such as the American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics provided guidance for updates to criteria for certain tests and the inclusion of new tests.

Following the January 2021 rules hearing and based on comment received, the Board voted to direct staff to continue working with interested parties to refine language around genetic counseling and certain prenatal tests. Board and Department staff worked to revise the proposed rule and developed a working draft based on comments received during the rules hearing. An informal comment period was held from March 8-19, 2021. Based on comment, staff have made policy and technical changes to the working draft. The working draft adds additional criteria for when certain prenatal tests

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should be covered and clarifies when pre- and post-procedure genetic counseling is required.

I have invited Samantha Pskowski, Board Staff, to provide a summary of the work done since January, share the comments that were received on the working draft rule, and to provide staff recommendations on how to address these comments.

There is no action for the Board to take on this item today.

Staff

Samantha Pskowski

To request this document in an alternate format or a different language, please contact Kelie Kahler, Washington State Board of Health Communication Manager, at 360-236-4102 or by email at kelie.kahler@sboh.wa.gov. TTY users can dial 711.

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