WASHINGTON STATE

Date: June 9, 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. A 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 proposed rule 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.

The Board received public comment on the proposed rule, expressing both support and concern around the costs of the proposed rule. In response to comments, continued engagement with interested parties and subject matter experts is underway to understand and address comments.

I have invited Samantha Pskowski, Board Staff, to provide a summary of the proposed changes, share the comments that were received on the proposed rule, and to provide

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staff recommendations on how to address these comments. Following this presentation, we will hold a public hearing on the rule and discuss the proposed changes.

Recommended Board Actions:

The Board may wish to consider, amend if necessary, and adopt one of the following motions:

The Board adopts the proposed amendments to chapter 246-680 WAC as published in WSR 21-10-077, with the revisions agreed upon at today's meeting, if any, and directs staff to file a CR-103 and establish an effective date of July 1, 2022.

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 <u>kelie.kahler@sboh.wa.gov.</u> TTY users can dial 711.

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