



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
Prevention and Community Health  
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TO: Michelle Davis, Executive Director  
Washington State Board of Health

FROM: *Allene Mares*  
Allene Mares, Assistant Secretary  
Division of Prevention and Community Health

SUBJECT: RULEMAKING REQUEST – WAC 246-680-010, -020 to review, clarify, and update the definitions and standards for screening and diagnostic tests during pregnancy.

The Department of Health is requesting the State Board of Health initiate rulemaking to consider defining current practice standards related to prenatal screening and diagnostic testing to establish clear health care guidelines and to clarify conflicting ambiguous language within the rule to ensure uniform interpretation. As part of the rulemaking, the Department of Health would consider the recommendations published by health policy organizations such as the American Congress of Obstetricians and Gynecologists and the American College of Medical Genetics for prenatal screening and diagnostic tests.

Currently, portions of Washington's Prenatal Screening rules are conflicting or ambiguous and require clarification in order to establish clear health care guidelines. There is confusion for the term "Prenatal carrier testing", which is defined in section 246-680-010, but is absent from the next section, 246-680-020 regarding standards for screening and diagnostic tests. The rule supports procedures for individuals who are genetic carriers, but fails to include identifying these carriers through carrier testing even though such testing is current standard of care.

Because the rule is conflicting, there have been instances of insurers not paying for the prenatal testing. This can potentially create a gap in insurance coverage, financial hardship, and promote health disparities. The decision to pursue any prenatal screening or diagnostic test remains up to the individual. By clearly defining standards for prenatal screening and diagnostic testing in the rule, we can improve health care access to women of child bearing age and their families.

All pregnancies have a 3-5% risk for a birth defect and may be at an additional risk for genetic disorders. Prenatal tests are available to provide information about some of these risks and can

help improve health outcomes. Prenatal screening and diagnostic testing can have a significant impact on pregnancies at risk for a genetic condition by:

- Enabling early diagnosis or preventative approaches to reduce the amount of resources needed for postnatal diagnosis of symptomatic children.
- Providing an opportunity to initiate appropriate health care services and interventions as soon as possible to improve the health of children and their families.
- Informing couples about health risks to current and future pregnancies to empower them to make informed pregnancy related health decisions.

Medical providers, insurers, testing laboratories, and women, men, and children could be impacted by changes to this rule. However we will know more after we compile recognized professional guidelines and best practices, identify all key stakeholders and content experts that could participate in this process, and hold public stakeholder workshops to solicit feedback on recommendations.

Please contact Deb Doyle, (253) 395-6742 or [Debra.LochnerDoyle@doh.wa.gov](mailto:Debra.LochnerDoyle@doh.wa.gov) if you have any questions.

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