



DATE: April 23, 2014

TO: Allene Mares, Assistant Secretary
Prevention and Community Health

FROM: Diana T. Yu, MD, MSPH, Chair 
Health Promotion Committee

SUBJECT: REQUEST FOR RULEMAKING FOR CHAPTER 246-680 WAC PRENATAL TESTS—CONGENITAL AND HERITABLE DISORDERS

Thank you for your memo dated February 13, 2014, requesting rule-making for Chapter 246-680-010 and 246-680-020 WAC to review, clarify, and update definitions and standards for screening and diagnostic tests during pregnancy. Your request was referred to the Washington State Board of Health's Health Promotion Committee at our March 2014 meeting. The Health Promotion Committee met and carefully reviewed your request.

At this time we are not sure that we will be able to open the rule due to capacity issues, as board members with medical expertise are already committed to a number of projects. As we reviewed your memo, we also realized that it would be helpful to have a fuller picture of the issues underlying your rule making request. We hope that your staff can help us sort through some of the questions and concerns that we have about prenatal genetic screening.

The committee recognizes that not all prenatal genetic screening tests are equally accurate or specific, and many conditions can be identified that are never expressed (such as Huntington's disease). Are there standards used to make determinations on genetic screening testing inclusion? If so, how are these standards applied, changed, and/or accepted? Is there a national group that has worked on prenatal carrier testing? If so, can you tell us more about the review process, the recommendations, and acceptance of those recommendations? Is there a national group that sets the standard for what is to be included in a prenatal screening test made available to all pregnant women?

The whole topic of prenatal screening and diagnostic testing is immense. Many tests are available commercially and unless there is a standard set for which tests are to be included, where do we begin? We have asked Board staff to look for information about the original intent of the legislation that led to the creation of Chapter 246-680-010 and 246-680-020 WAC. Specifically, we would like to know whether it was to make sure that prenatal screening is made available to all pregnant women, or was it to identify screening for diseases and conditions that cause physical defects, or genetic traits for potential diseases.

Our committee is committed to working to protect the health of Washington state residents. With regard to prenatal testing, we feel we must do due diligence to ensure that in addition to having standard screening tests available, we also have a process in place to respond to the results of the testing. We understand the importance of testing. However, we need to make sure we are not creating another health disparity and putting folks in limbo because they are now identified as a carrier of some type of genetic disorder. Are there adequate systems in place that provide follow up for affected folks, false positives and carriers? Paying for tests is a minor cost, compared to the costs of genetic counseling and follow up.

We appreciate your assistance to further clarify this rule request. Once we have more Board sponsor capacity, we can revisit this request. Defining the questions, setting standards (or adopting national standards) will help to improve the process that is used to add conditions/tests to this rule in the future.