DRAFT – Prenatal Screening (Chapter 246-680 WAC)
April 1, 2021

Statutory authorities: RCW 43.20.050, 48.21.244, 48.44.344, 48.46.375, and 70.54.220.

Recommended Rules by Part and Section Number	Section Title	Description of change	Rationale for Change (Clarity, Usability, Public Health Improvement, Consistency with Federal Rule or Guidance, Consistency with National Guidance, Other Rationale)
246-680-001	Purpose	No recommended changes.	
246-680-010	Definitions	(1) Removed "amniocentesis" from the umbrella definition of "prenatal test" and created a new definition. (2) Changed "prenatal carrier testing" to "carrier screening" and expanded the definition to include X-linked and recessive conditions. (3) Removed "chorionic villus sampling" from the umbrella definition of "prenatal test" and updated the timeframe for testing. (4) Removed "maternal hepatitis B surface antigen (HBsAg)" from the umbrella definition of "prenatal test" and created a new definition. (5) Removed "maternal serum marker screening" from the umbrella definition of "prenatal test" and updated the definition. (6) Removed "percutaneous umbilical blood sampling" from the umbrella definition of "prenatal test" and updated the definition. (7) Removed language "…under the direction of a physician". (8) Added a definition for "prenatal cell free DNA screening". (9) Simplified the definition of "prenatal test," and established a new definition for each test/procedure listed under this term. (10) No significant change. (11) Removed language "…under the direction of a physician". In addition to these changes, we removed the term "group B strep screening" from the definitions because the term was not used in the body of the rule. Language from that definition was moved to section 246-680-020. The definition for "qualified genetic counselor" was removed due to current standards for licensing, and the definition for "Department" was removed because it was not used in the rule. We also arranged the definitions alphabetically.	(1) Provides clarity. (2) Consistent with terminology in the field of clinical genetics. (3) Consistent with current clinical practice. (4) Consistent with standards of care. (5) Provides clarity. (6) Provides clarity and is consistent with standards of care. (7) Reflects that genetic counselors are now licensed and may practice independent of a physician. (8) Consistent with current clinical practice. (9) Provides clarity. (10) No significant change. (11) Reflects that genetic counselors are now licensed and may practice independent of a physician.
246-680-020	Standards for screening and diagnostic tests	(1) Added a new section for hepatitis B surface antigen screening and strep B strep screening to clarify that pre- and post-procedure genetic counseling is not required for these. (1)(b) Clarified the timeframe for screening. (2)(a) Modified the timeframe for maternal serum marker screening. (2)(b) Included prenatal ultrasonography for all women during the first trimester to establish viability, gestational age and determine if singleton or multiple births; and during second trimester for fetal morphology. (2)(c) Separated out routine ultrasonography from those required for	(1) Provides clarity for those prenatal tests which do not require pre- and post-procedure genetic counseling. (1)(b) Provides clarity. 2(a) Consistent with current standards of care. Provides clarity. 2(b)-(c) Provides clarity and consistency with current practice standards.

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		invasive testing or indicated by specific risk factors and detailed the risk factors. (2)(d) Updated the timeframe for amniocentesis. Omitted all prior reasons/indications listed for amniocentesis. (2)(e) Updated the timeframe for chorionic villus sampling and eliminated all prior reasons/indications. (2)(f) Added fetal diagnostic testing to include chromosome analysis, targeted cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH) for anyone undergoing an invasive diagnostic procedure. Added other genetic, biochemical or infectious disease testing when medically necessary due to an abnormal ultrasound finding or known family history of a birth defect or heritable disorder. Added CMA in the case of recurrent intrauterine fetal demise. 2(g) Added cell free DNA including time of screening and limited to aneuploidy but not limited by age or other risk factors. Requires documentation of pre-procedure genetic counseling and appointment for post-procedure genetic counseling. Clarifies not solely for purposes of determining sex of the fetus. 2(h) Added carrier screening for recessive or X-linked conditions if indicated by a positive family history and screening for specific conditions irrespective of family history. Allow for limiting to once per lifetime. 2(i) Added parental diagnostic testing to inform fetal testing when the results of parental testing will be used to guide decision making. 3(a) Omitted the phrase with preprocedure and postprocedure genetic counseling. Clarified language.	2(d) Provides clarity and consistency with current practice standards. 2(e) Provides clarity and consistency with current practice standards. 2(f) Provides clarity and consistency with current practice standards. 2(f) Clarify the standard testing for invasive procedures versus additional testing that may be warranted given abnormal screening results or positive family health history. 2(g) Updated to reflect current clinical practice. 2(h) Carrier screening is standard of care. The list included in the rule reflects those conditions most routinely utilized because of race/ethnicity and spinal muscular atrophy – endorsed by ACOG/ACMG. 2(i) Added to take into consideration that some fetal diagnostic tests can reveal uncertain results that must then be compared to parental findings. 3(a) Simplify the language.