WSR 21-16-076
PERMANENT RULES
STATE BOARD OF HEALTH

[Filed July 30, 2021, 3:55 p.m., effective July 1, 2022]

Effective Date of Rule: July 1, 2022.

Purpose: WAC 246-680-010 and 246-680-020, prenatal tests, congenital and heritable disorders. The purpose of the adopted rule is to update the state board of health's (board) existing rules outlining prenatal screenings and diagnostic tests required to be covered by certain payers to align with current clinical standards and best practices. The board's rule was most recently updated in 2003, and since such time, new screenings and diagnostics have become available and standards of practice have been revised. This adopted rule will increase access to certain prenatal screening and diagnostic testing for pregnant individuals.

Citation of Rules Affected by this Order: Amending WAC 246-680-010 and 246-680-020.

Statutory Authority for Adoption: RCW 43.20.050, 48.21.244, 48.44.344, 48.46.375, and 70.54.220.

Adopted under notice filed as WSR 20-24-119 [21-10-077] on May 3, 2021.

Changes Other than Editing from Proposed to Adopted Version: WAC 246-680-020 (2)(g)(ii) was amended, based on comment received during the public comment period, to remove the requirement for a follow-up appointment be scheduled for coverage of cell-free DNA testing and instead require documentation of how post-procedure counseling be provided.

A final cost-benefit analysis is available by contacting Samantha Pskowski, P.O. Box 47990, Olympia, WA 98540-7990, phone 360-789-2358, TTY 711, email samantha.pskowski@sboh.wa.gov, website https://sboh.wa.gov/Rulemaking/CurrentRulesandActivity/PrenatalTestsCongenitalandHeritableDisorders.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 2, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 2, Repealed 0.

Date Adopted: June 9, 2021.

Michelle A. Davis
Executive Director

OTS-1481.5

AMENDATORY SECTION (Amending WSR 03-11-031, filed 5/15/03, effective 6/15/03)

WAC 246-680-010 Definitions. ((~~For the purpose of this chapter, the following definitions apply:~~

~~(1) "Department" means the Washington state department of health.~~

~~(2) "Health care providers" means persons licensed or certified by the state of Washington under Title 18 RCW to provide prenatal care or to practice medicine and qualified genetic counselors.~~

~~(3) "Prenatal carrier testing" means a procedure to remove blood or other tissue from one or both parents in order to perform laboratory analysis to establish chromosome constitution or genetic carrier status of the parents.~~

~~(4)~~)) The definitions in this section apply throughout this chapter unless the context clearly requires otherwise:

(1) "Amniocentesis" means a procedure to remove a small amount of amniotic fluid from the uterus of a pregnant person in order to perform one or more of the following laboratory tests:

(a) Measure the level of alpha-fetoprotein;

(b) Measure the level of acetylcholinesterase;

(c) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);

(d) Biochemical studies on fetal cells or amniotic fluid;

(e) Deoxyribonucleic acid (DNA) studies on fetal cells for single gene disorders or fetal genotyping for isoimmunization studies; and

(f) Infectious disease studies.

(2) "Carrier screening" means a procedure to remove blood or other tissue from one or both parents in order to perform laboratory analysis to establish chromosome constitution or recessive or X-linked genetic carrier status of the parents.

(3) "Chorionic villus sampling" means a procedure to remove a small number of cells from the developing placenta, in order to perform one or more of the following laboratory tests:

(a) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);

(b) Biochemical studies on placental cells; and

(c) DNA studies on placental cells for single gene disorders.

(4) "Hepatitis B surface antigen (HBsAg) screening" means a procedure involving obtaining blood from a pregnant person to test for maternal hepatitis B infection.

(5) "Maternal serum marker screening" means a procedure involving obtaining blood from a pregnant person in order to measure through laboratory tests the level of certain products that are associated with increased risks to the fetus or pregnancy such as alpha-fetoprotein, unconjugated estriol, human gonadotropin, inhibin, or PAPP-A.

(6) "Percutaneous umbilical blood sampling" means a procedure to obtain blood from the fetus, in order to perform one or more of the following laboratory tests:

(a) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);

(b) Viral titer studies;

(c) Fetal blood typing for isoimmunization studies;

(d) Prenatal diagnostic tests for hematological disorders;

(e) DNA studies on fetal cells for single gene disorders; and

(f) Biochemical studies on fetal blood.

(7) "Postprocedure genetic counseling" means individual counseling that may be part of another procedure, or service involving a health care provider and a pregnant person with or without other family members, to discuss the results of the prenatal tests done, any further testing or procedures available or referrals for further consultation or counseling.

(8) "Prenatal cell free DNA screening," sometimes called noninvasive prenatal screening, means drawing blood from the pregnant person to perform laboratory analysis on the cell free DNA circulating in the maternal blood stream.

(9) "Prenatal test" means any test or procedure to ((~~predict~~)) screen for or diagnose congenital or heritable disorders ((~~that may harm or endanger the health, safety, or welfare of members of the public if improperly utilized and includes preprocedure and postprocedure genetic counseling, laboratory tests, and procedures as follows:~~

~~(a) Maternal serum marker screening is a procedure involving obtaining blood from a pregnant woman during the fifteenth to twenty-second week of gestation, in order to measure through laboratory tests the level of certain analytes that are associated with increased risks to the fetus or pregnancy such as alpha-fetoprotein, unconjugated estriol, human gonadotropin, inhibin, and/or PAPP-A.~~

~~(b) Maternal hepatitis B surface antigen (HBsAg) screening is a procedure involving obtaining blood from a pregnant woman during the first trimester of pregnancy to test for maternal hepatitis B infection. HBsAg screening should be repeated during the last trimester of pregnancy if a woman is at high risk for hepatitis B infection.~~

~~(c) Group B strep screening per vaginorectal culture at 35-37 weeks gestation is used to screen pregnant women for Group B strep colonization. The swab culture specimen must be grown in selective broth media.~~

~~(d) Amniocentesis is a procedure performed after fourteen weeks of gestation to remove a small amount of amniotic fluid from the uterus of a pregnant woman, in order to perform one or more of the following laboratory tests:~~

~~(i) Measure the level of alpha-fetoprotein;~~

~~(ii) Measure the level of acetylcholinesterase;~~

~~(iii) Cytogenetic studies on fetal cells including fluorescent in-situ hybridization (FISH) if indicated;~~

~~(iv) Biochemical studies on fetal cells or amniotic fluid;~~

~~(v) Deoxyribonucleic Acid (DNA) studies on fetal cells including fetal genotyping for isoimmunization studies; and~~

~~(vi) Infectious disease studies.~~

~~(e) Chorionic villus sampling is a procedure performed from ten to twelve weeks of gestation to remove a small amount of cells from the developing placenta, in order to perform one or more of the following laboratory tests:~~

~~(i) Cytogenetic studies on fetal cells including fluorescent in-situ hybridization (FISH) if indicated;~~

~~(ii) Biochemical studies on fetal cells; and~~

~~(iii) DNA studies on fetal cells.~~

~~(f) Percutaneous umbilical cord blood sampling is a procedure performed typically after fifteen weeks of gestation to obtain blood from the fetus, in order to perform one or more of the following laboratory tests:~~

~~(i) Cytogenetic studies including fluorescent in-situ hybridization (FISH) if indicated;~~

~~(ii) Viral titer studies;~~
~~(iii) Fetal blood typing for isoimmunization studies;~~
~~(iv) Prenatal diagnostic tests for hematological disorders;~~
~~(v) DNA studies on fetal cells;~~
~~(vi) Biochemical studies on fetal blood.~~
~~(g)~~)) of a fetus.

(10) "Prenatal ultrasonography ((~~is~~))" means a procedure ((~~performed at any time during pregnancy~~)) resulting in visualization of the uterus, the placenta, the fetus, and internal structures through use of sound waves.

((~~(h)~~)) (11) "Preprocedure genetic counseling" means individual counseling((~~, which~~)) that may be part of another procedure, or service, involving a health care provider ((~~or a qualified genetic counselor under the direction of a physician,~~)) and a pregnant ((~~woman~~)) person with or without other family members, to assess and identify increased risks for congenital abnormalities or pregnancy complications, offer specific carrier screening or diagnostic tests, discuss the purposes, risks, accuracy, and limitations of a prenatal testing procedure, aid in decision making and to assist, when necessary, in obtaining the desired testing or procedure.

((~~(i) "Postprocedure genetic counseling" means, when test results are available, individual counseling, which may be part of another procedure or service, involving a health care provider or a qualified genetic counselor under the direction of a physician and a pregnant woman with or without other family members, to discuss the results of the prenatal tests done, any further testing or procedures available and/or referrals for further consultation or counseling.~~

~~(j) "Qualified genetic counselor" means an individual eligible for certification or certified as defined by the American Board of Medical Genetics, Inc., or the American Board of Genetic Counseling.~~))

[Statutory Authority: RCW 48.21.244, 48.44.344, 48.46.375, 70.54.220. WSR 03-11-031, § 246-680-010, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050. WSR 91-02-051 (Order 124B), recodified as § 246-680-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 48.21.244, 48.44.344 and 48.46.375. WSR 90-02-094 (Order 024), § 248-106-010, filed 1/3/90, effective 2/3/90.]

AMENDATORY SECTION (Amending WSR 03-11-031, filed 5/15/03, effective 6/15/03)

WAC 246-680-020 Board of health standards for screening and diagnostic tests during pregnancy. (1) For the purpose of RCW 48.21.244, 48.44.344, and 48.46.375, the following are standards of medical necessity for insurers, health care service contractors, and health maintenance organizations to use when authorizing requests or claims for prenatal screening ((~~and/or~~)) or diagnosis without the requirement of a case-by-case determination:

(a) Hepatitis B surface antigen (HBsAg) screening for all pregnant persons during the first trimester of pregnancy and the last trimester of pregnancy if the person is at high risk for hepatitis B infection.

(b) Group B strep screening through prenatal vaginorectal cultures at thirty-five to thirty-seven weeks of gestation. Pregnant persons who are currently colonized with Group B strep, or who have un-

known Group B strep status should receive intrapartum treatment in accordance with the current standard of practice in order to reduce risk to the newborn.

(2) For the purpose of RCW 48.21.244, 48.44.344, and 48.46.375, the following are standards of medical necessity for insurers, health care service contractors, and health maintenance organizations to use when authorizing requests or claims for prenatal screening or diagnosis without the requirement of a case-by-case determination and including preprocedure and postprocedure genetic counseling:

(a) Maternal serum marker screening for all pregnant ((~~women~~)) persons at the beginning of prenatal care if initiated before the ((~~twentieth~~)) twenty-second completed week of gestation.

(b) ((~~Maternal hepatitis B surface antigen (HBsAg) screening for all pregnant women during the first trimester of pregnancy and the last trimester of pregnancy if the woman is at high risk for hepatitis B infection.~~

~~(c) Information about Group B strep should be provided to all pregnant women, including the risk to the newborn, if the woman is identified through screening as potentially colonized with Group B strep. Screening is done through prenatal vaginorectal cultures, although specific clinical indicators may preclude screening. Pregnant women who are currently colonized with Group B strep, or who have unknown Group B strep status should receive intrapartum treatment in accordance with the current standard of practice in order to reduce risk to the newborn.~~

~~(d)~~)) Prenatal ultrasonography:

(i) During the first trimester to establish viability, gestational age, and determine if singleton or multiple births; and

(ii) During second trimester for fetal morphology.

(c) Additional prenatal ultrasonography can be done at any time during a pregnancy if one or more of the following criteria are met:

(i) A ((~~woman~~)) person is undergoing amniocentesis, chorionic villus sampling, ((~~or~~)) percutaneous umbilical ((~~cord~~)) blood sampling, or fetal tissue biopsy;

(ii) The results of a maternal serum marker screening or prenatal cell free DNA test indicate an increased risk to the fetus or pregnancy;

(iii) ((~~A woman or the biological father of the fetus has a personal or family history of a congenital abnormality detectable by prenatal ultrasound;~~

~~(iv)~~)) There is an increased risk of a congenital abnormality ((~~is present~~)) due to:

(A) An environmental exposure ((~~including maternal exposure to alcohol; or~~

~~(v)~~));

(B) A medical evaluation ((~~indicates~~)) indicating the possibility of polyhydramnios ((~~or~~)), oligohydramnios, or poor or accelerated fetal growth; or

(C) A personal or family history of a congenital abnormality that is potentially detectable by prenatal ultrasound.

((~~(c)~~)) (d) Amniocentesis ((~~if one or more of the following criteria are met:~~

~~(i) A woman is thirty-five years of age or older at the time of delivery;~~

~~(ii) A woman or the biologic father of the fetus has a previous child or fetus with a chromosomal abnormality or other prenatally diagnosable disorder;~~

~~(iii) A woman or the biologic father of the fetus has a family history that includes birth defects or developmental delays;~~

~~(iv) A woman or the biologic father of the fetus is a carrier of a chromosomal rearrangement;~~

~~(v) A woman and/or the biologic father of the fetus are carriers of, or affected with, a prenatally diagnosable inherited disorder;~~

~~(vi) The results of a maternal serum marker screening test indicate an increased risk to the pregnancy or fetus;~~

~~(vii) A woman has a documented history of three or more miscarriages of unknown cause when circumstances prevent parental chromosomal testing;~~

~~(viii) There is an ultrasound diagnosis of fetal anomaly;~~

~~(ix) A medical evaluation indicates an increased risk of fetal infection;~~

~~(x) Fetal blood studies are indicated for isoimmunization studies or therapy.~~

~~(f)~~)) after fourteen weeks of gestation.

(e) Chorionic villus sampling ((~~with preprocedure and postprocedure genetic counseling if one or more of the following criteria are met:~~

~~(i) A woman is thirty-five years of age or older at the time of delivery;~~

~~(ii) A woman or the biologic father of the fetus has a previous child or fetus with a chromosomal abnormality or other prenatally diagnosable inherited disorder;~~

~~(iii) A woman or the biologic father of the fetus is a carrier of a chromosomal rearrangement;~~

~~(iv) A woman or the biologic father of the fetus is a carrier of, or affected with, a prenatally diagnosable inherited disorder;~~

~~(v) A woman has a documented history of three or more miscarriages of unknown cause when circumstances prevent parental chromosomal testing; or~~

~~(vi) Fetal genotyping is indicated to determine risks for isoimmunization.~~

~~(g)~~)) between ten and fourteen weeks of gestation.

(f) Fetal diagnostic testing including:

(i) Cytogenetic studies on fetal cells including chromosome analysis, targeted cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH) ((~~if a medical evaluation indicates a rapid or specific submicroscopic chromosomal diagnosis is required to predict the prognosis for the fetus~~)) for any person undergoing amniocentesis or chorionic villus sampling; and

(ii) DNA testing, biochemical testing, or testing for infectious diseases if medically indicated because of an abnormal ultrasound finding, intrauterine fetal demise, or known family history; and

(iii) Cytogenomic microarray analysis in the case of recurrent intrauterine fetal demise.

(g) Prenatal cell free DNA testing performed after nine weeks of gestation for the detection of aneuploidy including trisomy 21, 18, 13, or the sex chromosomes if the following criteria are met:

(i) There is documentation of preprocedure genetic counseling;

(ii) There is documentation of how postprocedure genetic counseling will be provided; and

(iii) Testing the sex chromosomes is not solely for the purposes of determining the sex of the fetus.

(h) Carrier screening at any time during the pregnancy for:

(i) Recessive or X-linked conditions if indicated by a positive family history; and

(ii) Any of the following conditions irrespective of family history:

(A) Alpha-thalassemia (HBA1/HBA2);

(B) Beta-thalassemia;

(C) Bloom syndrome;

(D) Canavan disease;

(E) Cystic fibrosis;

(F) Familial dysautonomia (IKBKAP);

(G) Fanconi anemia type C (FANCC);

(H) Gaucher disease (GBA);

(I) Mucolipidosis IV (MCOLN1); or

(J) Niemann-Pick disease (SMPD1);

(K) Sickle cell disease;

(L) Spinal muscular atrophy (SMN1);

(M) Tay-Sachs disease (HEXA);

(N) Fragile-X Syndrome.

(iii) Carrier screening under (h)(i) and (ii) of this subsection may be limited to once per lifetime.

(i) Molecular genetic or cytogenetic testing of parents to allow for definitive fetal testing, or parental testing to better inform results that are suggestive of, but do not identify a unifying diagnosis and when the results of the parental testing will be used to guide treatment, reproductive decisions, or care planning that would not otherwise be made.

((~~(2)~~)) (3) The ((~~board recommends the~~)) following ((~~additional~~)) procedures ((~~for use by insurers, health service contractors, and health maintenance organizations in determining medical necessity on a case-by-case basis~~)) are for use by insurers, health service contractors, and health maintenance organizations in determining medical necessity on a case-by-case basis to use when authorizing requests for claims for prenatal screening and diagnosis:

(a) Percutaneous umbilical cord blood sampling ((~~with preprocedure and postprocedure genetic counseling~~)) after fifteen weeks of gestation if one or more of the following criteria are met:

(i) A medical evaluation indicates rapid or specific submicroscopic chromosomal diagnosis or DNA diagnosis is required to predict prognosis for the fetus;

(ii) A medical evaluation indicates the possibility of a prenatally diagnosable fetal infection;

(iii) Fetal blood studies are medically indicated for isoimmunization studies or therapy;

(iv) Fetal blood is the only means to provide biochemical genetic diagnosis;

(v) Prenatal diagnosis of a hematological disorder is medically indicated.

(b) Prenatal tissue biopsy if the nature of the disorder in question indicates that fetal liver, skin, or other tissue biopsy is the only means to provide biochemical genetic diagnosis to protect the health of the ((~~mother~~)) pregnant person or predict the prognosis of the fetus.

(c) Cytogenomic microarray analysis (CMA) if medically indicated because of an abnormal ultrasound finding or known family history.

[Statutory Authority: RCW 48.21.244, 48.44.344, 48.46.375. WSR 03-11-031, § 246-680-020, filed 5/15/03, effective 6/15/03. Statutory

Authority: RCW 43.20.050. WSR 91-02-051 (Order 124B), recodified as § 246-680-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 48.21.244, 48.44.344 and 48.46.375. WSR 90-02-094 (Order 024), § 248-106-020, filed 1/3/90, effective 2/3/90.]