(Effective until July 1, 2022)

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) "Prenatal test" means any test to predict 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) Prenatal ultrasonography is 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) "Preprocedure genetic counseling" means 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 assess and identify increased risks for congenital abnormalities or pregnancy complications, offer specific carrier or diagnostic tests, discuss the purposes, risks, accuracy, and limitations of a prenatal testing procedure, aid in decision making and to assist 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.]

(Effective July 1, 2022)

WAC 246-680-010 Definitions. 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 screen for or diagnose congenital or heritable disorders of a fetus.

(10) "Prenatal ultrasonography" means a procedure resulting in visualization of the uterus, the placenta, the fetus, and internal structures through use of sound waves.

(11) "Preprocedure 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 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.

[Statutory Authority: RCW 43.20.050, 48.21.244, 48.44.344, 48.46.375 and 70.54.220. WSR 21-16-076, § 246-680-010, filed 7/30/21, effective 7/1/22. 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.]