PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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DATE: December 02, 2020
TIME: 8:09 AM

WSR 20-24-119

Agency: State Board of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 18-24-016 **; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR ; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☐ **Proposal is exempt under RCW .**

Title of rule and other identifying information: (describe subject) Chapter 246-680 WAC -Prenatal Tests - Congenital and Heritable Disorders. The State Board of Health (Board) is proposing rules to align the prenatal screening and diagnostic tests that are considered medically necessary, and align with current national standards of care and current best practices. The screening and diagnostic tests in this rule are required to be included by certain insurers when authorizing requests or claims for prenatal screening or diagnosis without the requirement of a case by case determination.

Hearing location(s):			
Date:	**Time:**	**Location:** (be specific)	**Comment:**
01/13/2021	11:30 A.M.	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the State Board of Health will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical space, will be held instead. Board member, presenters, and staff will all participate remotely. The public may login using a computer or device, or call-in using a phone to listen to the meeting through the Go To Webinar application. The public may submit verbal comments during the specified rules hearing segment. To access the meeting online and register: https://attendee.gotowebinar.com/register/5800879722876316428 You can also dial-in and listen/observe only using your phone: Call: +1 (415) 655-0060 Access Code: 750-060-889	

Date of intended adoption: 01/13/2021 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Samantha Pskowski
Address: P.O. Box 47990
Olympia, WA
98504-7990
Email: https://fortress.wa.gov/doh/policyreview
Fax: N/A
Other: None
By (date) 01/06/2021

Assistance for persons with disabilities:

Contact Samantha Pskowski
Phone: (360) 789-2358
Fax:
TTY: 711
Email: samantha.pskowski@sboh.wa.gov
Other:
By (date) 01/08/2021

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this proposal is to update the Board's existing rules setting forth prenatal screenings and diagnostic tests to be covered by certain payers without a case by case determination, 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 proposal would increase access to certain prenatal screening and diagnostic testing for pregnant individuals.

Reasons supporting proposal: There have been many advances in prenatal screening over the years. These newer procedures offer better detection rates for birth defects or genetic conditions, as well as lower false positive rates. The purpose of the proposed rule is to continue to ensure equity for accessing prenatal screening and diagnostic services for women that choose them and to bring the rule into alignment with national standards of care and current best practices.

In 1988, the Washington State Legislature passed legislation that (1) required healthcare providers treating pregnant women to inform them about the availability of prenatal screening and testing options (RCW 70.54.220); (2) required multiple payers to cover such services (RCW 48.21.244, 48.44.344 and 48.46.375); and (3) placed limitations on certain payers to ensure they did not cancel, reduce, or alter coverage provided solely based on results of a prenatal test (RCW 48.42.090). The Board has the authority to establish standards in rule for screening and diagnostic procedures during pregnancy when those services are determined to be medically necessary. The regulations were written to eliminate the coercive and unethical practices of some payers who offered to cover the costs of prenatal screening and diagnostic procedures only if patients signed an agreement that they would terminate the pregnancy if an abnormality was found.

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

Statutory authority for adoption: RCW 43.20.050, RCW 48.21.244, RCW 48.44.344, RCW 48.46.375, and RCW 70.54.220

Statute being implemented: RCW 70.54.220, RCW 43.20.050, RCW 48.44.344, RCW 48.21.244, and RCW 48.46.375

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Washington State Board of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358
Implementation:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358
Enforcement:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Samantha Pskowski
Address: P.O. Box 47990
Olympia, WA
98504-7990
Phone: (360) 789-2358
Fax: N/A
TTY: 711
Email: samantha.pskowski@sboh.wa.gov
Other:

☐ No: Please explain:

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's analysis showing how costs were calculated. The cost threshold for the industry of Direct Health and Medical Insurance Carriers is $216,158.22. It has been determined that there are no small businesses in the Direct Health and Medical Insurance Carriers industry and therefore this proposal does not require an SBEIS, however it has been determined through the following that the proposed rule does exceed the average cost threshold for this industry.

To calculate the total cost of the rule, first an estimated population of those who will utilize the expanded prenatal screening and diagnostic testing must be determined. To estimate this population, first the total population covered under health coverage subject to this rule was estimated using available state and national data. In 2018, 52% of Washingtonians were covered by an employer-sponsored plan. A 2011 report estimated that 56% of Washingtonians covered under employer plans were in self-funded plans, not subject to this rule (https://www.shrm.org/ResourcesAndTools/hr-topics/benefits/Documents/EBRI_Notes_11_Nov-12.Slf-Insrd1.pdf).

Using the estimated population of Washington State in 2018 (7,524,000) this would include approximately 1,721,491 individuals in employer sponsored plans applicable to this rule, with an additional 451,440 individuals in non-group plans subject to the rules. Using a per capita rate of 1,376 pregnancies per 100,000 residents (103,557 pregnancies / 7,524,000 population * 100,000), it can be estimated there would be 29,900 pregnancies annually in the population subject to this rule; (2,172,931 total population / 100,000) * 1,376.

We do not have a way of knowing how many women will utilize each prenatal screening or diagnostic test. To estimate the number of tests with the estimated for the estimated population above, we assume one for the number of births in 2018 with prenatal care in the first or second trimester was used as the base population. Using a 2014 study showing the percent of women who opt-in to prenatal screening when receiving care standards, the base population was multiplied by 12.3% (Kuppermann M, Pena S, Bishop JT, et al. Effect of Enhanced Information, Values Clarification, and Removal of Financial Barriers on Use of Prenatal Genetic Testing: A Randomized Clinical Trial. JAMA. 2014;312(12):1210-1217. doi:10.1001/jama.2014.11479). This resulted in an estimated 12,106 individuals receiving prenatal screenings and diagnostic testing (98,428 * 0.123). Because we are unable to determine how many individuals would receive each individual test, this entire population was assumed to receive each test.

The cost of expanding access to certain prenatal screenings and diagnostic testing has been determined to be approximately $41,704,842.

We do not have a way of knowing how many of the individual tests will be funded by an individual insurer, so we estimate an even distribution across the 68 entities. Therefore, we calculated an average cost per entity to be $613,306.50 (total cost to industry / total entities).

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: 12/01/2020	**Signature:**  Place signature here
Name: Michelle A. Davis	
Title: Executive Director	

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

(5) "Maternal serum marker screening" means a procedure involving obtaining blood from a pregnant woman 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 woman 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 mother to perform laboratory analysis on the cell free DNA circulating in the maternal blood stream.

(9) "Prenatal test" means any test 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 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 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.~~))

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 and including preprocedure and postprocedure genetic counseling:

(a) Maternal serum marker screening for all pregnant women 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.~~)) Group B strep screening ((~~is done~~)) through prenatal vaginorectal cultures((~~, although specific clinical indicators may preclude screening~~)) at thirty-five to thirty-seven weeks of gestation. 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.

(e) 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 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 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.

((~~(e)~~)) (f) 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.

(g) 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.

(h) Fetal diagnostic testing including:

(i) Cytogenetic studies on fetal cells including chromosome analysis, 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 woman undergoing amniocentesis or chorionic villus sampling; and

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

(i) 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.

(j) 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).

(k) Molecular genetic or cytogenetic testing of parents to allow for definitive fetal testing, or parental testing to better inform results when fetal testing results yield uncertain significance.

(2) The ((~~board recommends the~~)) following ((~~additional~~)) procedures ((~~for use by insurers, health service contractors, and health maintenance organizations in~~)) are used on a case-by-case basis for determining medical necessity ((~~on a case-by-case basis~~)) for insur-

ers, health service contractors, and health maintenance organizations 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 or predict the prognosis of the fetus.