

TITLE 17. PUBLIC HEALTH
DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES
CHAPTER 4. PREVENTIVE MEDICAL SERVICE
SUBCHAPTER 9. TESTING FOR HERITABLE DISORDERS
GROUP 5. CALIFORNIA PRENATAL SCREENING PROGRAM
ARTICLE 1. DEFINITIONS

Section 6520. Definitions.

(a) For the purposes of this Group, the following definitions apply:

(1) “Active Candidate” means a person who has received written notification from a certifying agency or board that the professional specialty eligibility criteria of the certifying agency or board was met and may take the first available certification examination, but they have not been certified by the certifying agency or board.

(2) “Adverse Outcome Data” means the information required to be collected following consecutive prenatal diagnostic procedures performed on ~~women~~ individuals planning to continue their pregnancies by Amniocentesis Practitioners, Transabdominal Chorionic Villus Sampling Practitioners, and Transcervical Chorionic Villus Sampling Practitioners. It must also be included in progress reports of Adverse Outcome Studies submitted to the Department by State-approved Comprehensive Prenatal Diagnosis Centers for each of their practitioners, under the conditions and intervals stated in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(3) “Adverse Outcome Studies” means the participation in the collection and reporting of Adverse Outcome Data and pregnancy information from consecutive prenatal diagnostic procedures performed on ~~women~~ individuals planning to continue their pregnancies by Amniocentesis Practitioners, Transabdominal Chorionic Villus Sampling Practitioners, and Transcervical Chorionic Villus Sampling Practitioners, under the conditions and intervals stated in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(4) “Amniocentesis Practitioner” means a physician who has a valid California medical license and is in good standing with the California Medical Board, is approved by the Department to perform second trimester ultrasound guided amniocentesis procedures for California Prenatal Screening

Program patients at State-approved Comprehensive and Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Board Certification by the American Board of Obstetrics and Gynecology (ABOG) or American Osteopathic Board of Obstetrics and Gynecology (AOBOG), or having Active Candidate status for the next ~~American Board of Obstetrics and Gynecology~~ certification exam; and

(B) Performance of 25 second trimester procedures on ~~women~~ individuals planning to continue their pregnancies with on-site supervision in the procedure room by an Obstetrician-Gynecologist experienced in ultrasound-guided amniocentesis, as defined in subsection 6520(a)(23); and

(C) Annual volume requirements for performance of amniocentesis procedures and participation in any required Adverse Outcome Studies, and all requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(5) "Analyte" means any constituent or substance the concentration of which is related to the presence of a birth defect and is analyzed and reported by prenatal birth defects screening laboratories as part of the California Prenatal Screening Program, including maternal serum alpha-fetoprotein, ~~human chorionic gonadotropin, unconjugated estriol, dimeric inhibin-A, and pregnancy-associated plasma protein A.~~

(6) "Applicant" means the entity applying for Departmental approval as a State-approved Comprehensive Prenatal Diagnosis Center, or to operate a State-approved Satellite Prenatal Diagnosis Center, and includes the individual who signs the application for approval.

(7) "Appointment Scheduler" means the staff person, or persons, designated by a Director of a State-approved Comprehensive Prenatal Diagnosis Center, and approved by the Department, as having met the requirements to manage appointment information for California Prenatal Screening Program referrals and results in the Department's Screening Information System for authorized follow-up services at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

(8) "Back-up Prenatal Diagnosis Center Contact Person" means the staff person designated by a Director of a State-approved Comprehensive Prenatal Diagnosis Center to act, in the absence of

the Prenatal Diagnosis Center Contact Person, and after the Department advised of the absence, as the Prenatal Diagnosis Center Contact Person.

(9) “Birth defect” means any functional or structural defect or genetic condition that is capable of being prenatally detected and for which the Department has a surveillance or screening program, including neural tube defects, ventral wall defects, and chromosomal defects.

(10) “California Prenatal Screening Program” (~~formerly known as the Expanded Alpha-fetoprotein Screening Program or Expanded AFP Screening Program~~) means the Department’s legislatively-mandated, state-wide program that includes maternal plasma and serum test(s) for prenatal screening for birth defects and authorized follow-up services for ~~women~~ individuals with a screen positive test.

(11) “Cell-free DNA screening” means a prenatal screening test for autosomal trisomies performed on maternal plasma. ~~serum for the detection of cell-free DNA to determine risk for fetal aneuploidies, and is authorized by the Department as a follow-up service for California Prenatal Screening Program patients.~~

(12) “Clinical Cytogeneticist” means a physician, or person holding a doctorate degree, who has California licensure as a Clinical Cytogeneticist and Board Certification by the American Board of Medical Genetics and Genomics or Canadian College of Medical Genetics in Clinical Cytogenetics.

(13) “Clinical Geneticist” means a physician who has a valid California medical license and is in good standing with the California Medical Board, and Board Certification by the American Board of Medical Genetics and Genomics in Clinical Genetics, or who has Active Candidate status for the next American Board of Medical Genetics and Genomics certification examination for Clinical Genetics. The physician must also be approved by the Department to provide consultation in person, supervise all professional services, and be responsible for the evaluation of work performance by reviewing and signing off on all patient charts for California Prenatal Screening Program patients at State-approved Comprehensive and Satellite Prenatal Diagnosis Centers.

(14) “Clinician” means physician, physician assistant, nurse midwife, nurse practitioner or any other person licensed or certified by the State to provide prenatal care to pregnant ~~women~~ individuals or to practice medicine.

(15) “Consultative Sonologist” means a physician who has a valid California medical license and is in good standing with the California Medical Board, is approved by the Department to perform first

or second trimester ultrasound examinations for California Prenatal Screening Program patients at State-approved Comprehensive and Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

- (A) Board certification or having Active Candidate status in Radiology by the American Board of Radiology or in Obstetrics and Gynecology by the ~~American Board of Obstetrics and Gynecology~~ ABOG or AOBOG; and
- (B) Completion of a fellowship and supplemental subspecialty training in maternal/fetal medicine; clinical genetics, with an emphasis upon fetal medicine; or diagnostic radiology, body imaging or the equivalent, with an emphasis upon fetal medicine, at a facility that performs at least 2,000 second trimester fetal ultrasound exams a year that meet the anatomical guidelines of the American Institute of Ultrasound in Medicine and American College of Radiology for complete fetal examinations. The supplemental training must include at least three months of targeted fetal ultrasound examinations that involve high-risk obstetric imaging that include basic physics, techniques, performance, and interpretation followed by three months of proctoring (co-reading) by a qualified consultative sonologist; and
- (C) Performance of at least 500 detailed second trimester ultrasound examinations on patients referred specifically for the detection of fetal abnormalities; and
- (D) Affiliation with an ultrasound practice at a State-approved Comprehensive and/or Satellite Prenatal Diagnosis Center that is accredited by the American College of Radiology or the American Institute of Ultrasound in Medicine; and
- (E) Annual volume requirements for performance of second trimester ultrasound examination procedures and all requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(16) “Cytogenetic test” means a laboratory test, such as karyotyping, on amniotic fluid or chorionic villus samples that enables visualization of fetal chromosomes for the detection of abnormalities and is authorized by the Department to be ordered by a State-approved Comprehensive or Satellite Prenatal Diagnosis Center for California Prenatal Screening Program patients.

(17) “Cytogenomic test” means a laboratory test, such as microarray, on amniotic fluid or chorionic villus samples that utilizes molecular diagnostic technology for the high resolution detection of fetal chromosomal abnormalities, and is authorized by the Department to be ordered by a State-approved

Comprehensive or Satellite Prenatal Diagnosis Center for California Prenatal Screening Program patients.

(18) “Department” means the California Department of Public Health.

(19) “Diagnostic tests and procedures” mean those additional tests, methods, examinations, or activities, approved by the Department to be performed consequent to a screen positive test, and are used to detect the presence of a birth defect of the fetus.

(20) “Director of a State-approved Comprehensive Prenatal Diagnosis Center” means the staff person at each State-approved Comprehensive Prenatal Diagnosis Center who is responsible for the supervision and the quality of testing, counseling, and medical care provided by all clinical members of that Center’s staff, and all of its affiliated State-approved Satellite Prenatal Diagnosis Centers, and for ensuring compliance with all provisions of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(21) “Experienced in transabdominal chorionic villus sampling” means having performed at least 25 first trimester transabdominal chorionic villus sampling procedures on ~~women~~ individuals planning to continue their pregnancies.

(22) “Experienced in transcervical chorionic villus sampling” means having performed at least 25 first trimester transcervical chorionic villus sampling procedures on ~~women~~ individuals planning to continue their pregnancies.

(23) “Experienced in ultrasound-guided amniocentesis” means having performed at least 25 second trimester ultrasound-guided amniocentesis procedures on ~~women~~ individuals planning to continue their pregnancies.

(24) “Follow-up services” means the procedures, services, and diagnostic and other approved tests meeting the standard of care as recommended by nationally recognized medical or genetic organizations and adopted by the Department and authorized consequent to a screen positive test result, and provided through State-approved Comprehensive and State-approved Satellite Prenatal Diagnosis Centers. Authorized follow-up services may include chorionic villus sampling or amniocentesis and related diagnostic tests, ultrasound, and genetic counseling.

(25) “Genetic Counselor” means an individual who has a current and valid genetic counselor license or temporary genetic counselor license issued by the Department and is approved by the Department

to provide genetic counseling services for California Prenatal Screening Program patients at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers.

(26) “Gestation” means the number of days elapsed since the first day of the last normal menstrual period. Gestational age may be calculated as the number of days from known or suspected conception plus 14 days or estimated by ultrasound examination and measurements or physical examination and measurements of a pregnant ~~woman~~ individual.

(27) “Inadequate specimen for cell-free DNA screening” means a blood specimen collected from a pregnant ~~woman~~ individual which is not suitable in quality or quantity, a blood specimen was collected before the ~~70th~~ 70 days (10 weeks 0 days) or after the ~~140th~~ day of gestation, or ~~was not documented with the clinical information~~ was not documented as required necessary for test result interpretation to perform valid prenatal screening for ~~birth defects~~ autosomal trisomies of the fetus.

(28) “Inadequate specimen for maternal serum alpha-fetoprotein screening” means a blood specimen collected from a pregnant individual which is not suitable in quality or quantity, a blood specimen collected before 15 weeks 0 days (105 days) or after 21 weeks 0 days (147 days) of gestation, or clinical information was not documented for test result interpretation to perform valid prenatal screening for neural tube defects of the fetus.

~~(28)~~(29) “Interim Approval Amniocentesis Practitioner” means a physician who has a valid California medical license and is in good standing with the California Medical Board, is approved by the Department to perform second trimester ultrasound-guided amniocentesis procedures for California Prenatal Screening Program patients under the supervision of an Amniocentesis Practitioner at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Completion of a Maternal-Fetal Medicine or equivalent specialized training program, or current participation in a Maternal-Fetal Medicine or equivalent specialized training program; and

(B) Performance of at least 10 second trimester amniocentesis procedures on ~~women~~ individuals planning to continue their pregnancies with on-site supervision in the procedure room by an Obstetrician-Gynecologist who is experienced in second trimester ultrasound-guided amniocentesis, as defined in subsection 6520 (a) (23), and is immediately adjacent to the practitioner during the procedures; and

(C) Annual volume requirements for performance of amniocentesis procedures, including submission of logs of supervised procedures, participation in any required Adverse Outcome Studies, and all requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

~~(29)~~ (30) “Interim Approval Transabdominal Chorionic Villus Sampling Practitioner” means a physician who has a valid California medical license and is in good standing with the California Medical Board, is approved by the Department to perform first trimester transabdominal chorionic villus sampling procedures for California Prenatal Screening Program patients under the supervision of a Transabdominal Chorionic Villus Sampling Practitioner at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Completion of a Maternal-Fetal Medicine or equivalent specialized training program, or current participation in a Maternal-Fetal Medicine or equivalent specialized training program; and

(B) Performance of at least 12 first trimester transabdominal chorionic villus sampling procedures on ~~women~~ individuals planning to continue their pregnancies with on-site supervision in the procedure room by an Obstetrician-Gynecologist who is experienced in transabdominal chorionic villus sampling, as defined in subsection 6520(a)(21), and is immediately adjacent to the practitioner during the procedures; and

(C) Annual volume requirements for performance of first trimester transabdominal chorionic villus sampling procedures, including submission of logs of supervised procedures, participation in any required Adverse Outcome Studies, and all requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

~~(30)~~ (31) “Interim Approval Transcervical Chorionic Villus Sampling Practitioner” means a physician who has a valid California medical license and is in good standing with the California Medical Board, is approved by the Department to perform first trimester transcervical chorionic villus sampling procedures for California Prenatal Screening Program patients under the supervision of a Transcervical Chorionic Villus Sampling Practitioner at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Completion of a Maternal-Fetal Medicine or equivalent specialized training program, or current participation in a Maternal-Fetal Medicine or equivalent specialized training program; and

(B) Performance of at least 12 first trimester transcervical chorionic villus sampling procedures on ~~women~~ individuals planning to continue their pregnancies with on-site supervision in the procedure room by an Obstetrician-Gynecologist who is experienced in transcervical chorionic villus sampling, as defined in subsection 6520 (a)(22), and is immediately adjacent to the practitioner during the procedures; and

(C) Annual volume requirements for performance of first trimester transabdominal chorionic villus sampling procedures, including submission of logs of supervised procedures, participation in any required Adverse Outcome Studies, and all requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

~~(31)~~ (32) “Internal Continuous Quality Improvement Program” means the Internal Continuous Quality Improvement Program at a State-approved Comprehensive Prenatal Diagnosis Center, and any State-approved Satellite Prenatal Diagnosis Centers, that is overseen by the Director of a State-approved Comprehensive Prenatal Diagnosis Center to achieve improvement goals, as required by the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

~~(32)~~ (33) “Invoice Liaison” means the staff person, or persons, designated by a Director of a State-approved Comprehensive Prenatal Diagnosis Center, and approved by the Department, as having met the requirements to manage invoicing in the Department’s Screening Information System for patient services provided for California Prenatal Screening Program referrals at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

(34) “Maternal Serum Alpha Fetoprotein screening” means a prenatal screening test on maternal serum for the determination of risk for fetal neural tube defects.

~~(33)~~ (35) “Method” means the instruments, devices, reagents, steps, and procedures used in a laboratory to measure the concentration of analytes in samples of maternal plasma or serum or amniotic fluid, or to perform prenatal diagnostic or other approved tests meeting the standard of care as recommended by nationally recognized medical or genetic organizations and adopted by the Department.

~~(34)~~ (36) "Patient Service Reports" means the electronic forms generated in the Department's Screening Information System to summarize of the status of the follow-up services authorized by the Department for California Prenatal Screening Program referrals and for the input of results of services provided for reimbursement of authorized follow-up services at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

~~(35)~~ (37) "Patient Service Reports Contact" means the staff person, or persons, designated by a Director of a State-approved Comprehensive Prenatal Diagnosis Center, and approved by the Department, as having met the requirements to enter data to complete Patient Service Reports in the Department's Screening Information System for California Prenatal Screening Program referrals at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

~~(36)~~ (38) "Prenatal birth defects screening laboratory" means a laboratory approved by the Department to conduct prenatal screening ~~laboratory tests to determine the~~ for autosomal trisomies or prenatal screening for neural tube defects ~~concentration of analytes in maternal serum and perform other analysis related to birth defects specified~~ as part of state administered testing.

~~(37)~~ (39) "Prenatal Diagnosis Center Contact Person" means the staff person designated by a Director of a State-approved Comprehensive Prenatal Diagnosis Center as the liaison to receive Departmental communications and distribute this information to Prenatal Diagnosis Center staff. This staff person will also report to the Department any changes in names, schedules, addresses, or telephone and facsimile numbers; and request changes in staff designated to perform required functions at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

(40) "Prenatal screening for autosomal trisomies" means a plasma screening test provided by a Department-approved prenatal birth defects screening laboratory (or laboratories) for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome) during pregnancy.

~~(38)~~ (41) "Prenatal screening for ~~birth~~ neural tube defects" means ~~a the sequence of~~ maternal serum screening tests ~~authorized by the Department and~~ provided by Department-approved prenatal birth defects screening laboratories. Serum screening consists of a tests for maternal serum alpha-

~~fetoprotein, human chorionic gonadotropin, unconjugated estriol, dimeric inhibin-A, and pregnancy-associated plasma protein-A in the first and/or second trimester of pregnancy.~~

~~(39)~~ (42) “Quarterly Report Contact Person” means the staff person designated by a Director of a State-approved Comprehensive Prenatal Diagnosis Center to enter prenatal diagnostic data on patients not referred by the California Prenatal Screening Program in the Department's Screening Information System at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

~~(40)~~ (43) “Screening Information System” means the computerized system used by the Department and external stakeholders for the management of screening data and patient service records.

~~(41)~~ (44) “Screen positive test result” means a screening test result that indicates an individual has an increased risk for the targeted condition based on screening conducted by Department-approved prenatal birth defects screening laboratories and is now eligible for follow-up services through the California Prenatal Screening Program ~~a screening test of a specimen performed by a prenatal birth defects screening laboratory which gives a positive result for reporting purposes pursuant to this Group.~~

~~(42)~~ (45) “State-approved Comprehensive Prenatal Diagnosis Center” means any facility which is approved by, and enters a contract with, the Department to provide and be reimbursed for diagnostic tests and procedures for the prenatal evaluation or detection of genetic diseases, disorders, and birth defects of the fetus, and other authorized follow-up services.

~~(43)~~ (46) “State-approved Satellite Prenatal Diagnosis Center” means a facility that has a written agreement with a State-approved Comprehensive Prenatal Diagnosis Center and is approved by the Department to provide authorized follow-up services at a site which is not in the same suite as an existing State-approved Comprehensive Prenatal Diagnosis Center or State-approved Satellite Prenatal Diagnosis Center.

~~(44)~~ (47) “Transabdominal Chorionic Villus Sampling Practitioner” means a physician who has a valid California medical license and is in good standing with the California Medical Board, is approved by the Department to perform first trimester transabdominal chorionic villus sampling procedures for California Prenatal Screening Program patients at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Board Certification by ~~the American Board of Obstetrics and Gynecology~~ ABOG or AOBOG, or having Active Candidate status for the next certification examination; and

(B) Approval as an Amniocentesis Practitioner; and

i. Performance of at least 25 first trimester transabdominal chorionic villus sampling procedures, with a minimum of five first trimester transabdominal chorionic villus sampling procedures performed on ~~women~~ individuals referred for prenatal genetic indications and planning to continue their pregnancies. All procedures performed on continuing pregnancies must have on-site supervision in the procedure room by an Obstetrician-Gynecologist who is experienced in transabdominal chorionic villus sampling, as defined in subsection 6520 (a)(21); or

ii. Approval as a Transcervical Chorionic Villus Sampling Practitioner; or

iii. Meeting the requirements for approval as a Transcervical Chorionic Villus Sampling Practitioner and Amniocentesis Practitioner; and

(C) Annual volume of transabdominal chorionic villus sampling procedures, participation in any required Adverse Outcome Studies, and any other requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

~~(45)~~ (48) “Transcervical Chorionic Villus Sampling Practitioner” means a physician who has a valid California medical license and is good standing with the California Medical Board, is approved by the Department to perform first trimester transcervical chorionic villus sampling procedures for California Prenatal Screening Program patients at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Board Certification by ~~the American Board of Obstetrics and Gynecology~~ ABOG or AOBOG, or having Active Candidate status for the next certification examination; and

(B) Performance of at least 25 first trimester transcervical chorionic villus sampling procedures, with a minimum of five first trimester transcervical chorionic villus sampling procedures performed on ~~women~~ individuals referred for prenatal genetic indications and planning to continue their pregnancies. All procedures performed on continuing pregnancies must have on-site supervision in the procedure room by an Obstetrician-Gynecologist who is experienced in transcervical chorionic villus sampling, as defined in subsection 6520(a)(22); and

(C) Approval as a Transabdominal Chorionic Villus Sampling Practitioner or meeting the requirements for approval as a Transabdominal Chorionic Villus Sampling Practitioner; and
(D) Annual volume of transcervical chorionic villus sampling procedures, participation in any required Adverse Outcome Studies, and any other requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

~~(46)~~ (49) “Ultrasound Accreditation Certificate” means the certification issued to an accredited ultrasound practice by the American Institute of Ultrasound in Medicine or the American College of Radiology.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124975, 124977, 124980, 124990, 125000, 125001, 125050, 125055, 125065 and 125070, Health and Safety Code.

ARTICLE 3. TESTING AND FOLLOW UP PROGRAM REQUIREMENTS

Section 6523. Prenatal Birth Defects Screening Laboratories and Analytical Methods.

(a) The Department shall approve prenatal birth defects screening laboratories. Such laboratories shall be licensed as clinical laboratories under Division 2, Chapter 3 (commencing with Section 1200) of the Business and Professions Code.

(b) Approved prenatal birth defects screening laboratories shall be limited to the following:

(1) A laboratory shall have obtained a contract from the Department under applicable laws and regulations to provide laboratory services in sufficient volume to provide the prenatal birth defects screening tests to all pregnant women individuals, in a designated geographic area defined by the Department, in a quantity specified in their contract, plus an emergency testing capacity that will be specified by contract. ~~The Department will define not more than 6 geographic areas and may combine geographic areas if necessary to reduce costs or assure statewide coverage.~~

(2) A laboratory exclusively serving a comprehensive prepaid group practice or health care service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available may be approved for testing consistent with the terms of a mutually acceptable contract for services with the Department.

(c) Prenatal birth defects screening laboratories approved by the Department shall comply with all laboratory standards for quality assurance issued by the Department and shall participate in a proficiency testing program approved and/or conducted by the Department and shall maintain levels of performance acceptable to the Department.

(d) Analytical methods to be used in the measurement of ~~each analyte~~ maternal serum alpha-fetoprotein concentration ~~in maternal serum~~ shall be designated and/or approved by the Department. Analytical methods to be used in the determination of chromosomal risk assessment and interpretations shall be designed and/or approved by the Department.

(e) Only Department approved prenatal screening laboratories ~~No laboratory~~ shall offer or provide prenatal screening for birth defects that are included in the Department's Prenatal Screening Program to California residents ~~without having obtained prior approval from the Department as a prenatal birth defects screening laboratory.~~

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125070, Health and Safety Code.

Section 6525. State-Approved Comprehensive and Satellite Prenatal Diagnosis Centers.

(a) State-approved Comprehensive and Satellite Prenatal Diagnosis Centers shall be limited to those facilities that have Department approval to provide authorized follow-up services. The Department shall approve prenatal diagnosis and other methods, and shall institute such quality control and proficiency testing as is necessary to assure the accuracy of testing ordered by State-approved Comprehensive and Satellite Prenatal Diagnosis Centers.

(b) State-approved Comprehensive and Satellite Prenatal Diagnosis Centers shall comply with all standards for quality assurance issued by the Department and shall maintain levels of performance and quality of services acceptable to the Department, as published in Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(c) The Department shall provide reimbursement for all authorized prenatal screening follow-up services performed consequent to a screen positive test result provided at any State-approved Comprehensive and Satellite Prenatal Diagnosis Centers.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6527. Clinician Requirements.

(a) Clinicians shall provide or cause to be provided to all pregnant ~~women~~ individuals in their care before ~~the 140th day~~ 21 weeks 0 days (147 days) of gestation, or before ~~the 126th day~~ 19 weeks 0 days (133 days) from conception, as estimated by medical history or clinical testing, information regarding the California Prenatal Screening Program. This information shall be in a format provided

by the Department and shall be given at the first prenatal visit and discussed with each pregnant ~~woman~~ individual.

(b) The provisions of subsection (a) shall not apply if the pregnant ~~woman~~ individual has completed more than ~~140 days~~ 21 weeks 0 days (147 days) of gestation or ~~126 days~~ 19 weeks 0 days (133 days) post conception, as estimated by medical history or clinical testing, and this fact is entered in the medical record.

(c) Clinicians shall cause to be provided to all pregnant ~~women~~ individuals who, after being provided with the information pursuant to subsection (a), voluntarily request to participate in the California Prenatal Screening Program and receive prenatal screening for ~~birth defects of the fetus~~ autosomal trisomies and/or prenatal screening for neural tube defects, the opportunity, the circumstances of which are to be documented in the medical record, to read and sign an ~~informed~~ consent document in a format provided by the Department. Maternal plasma and serum specimens must be accompanied by the pregnant individual's signed and Department-designated consent form to be analyzed for screening.

(d) If the pregnant ~~woman~~ individual consents to testing, the clinician shall arrange for prenatal screening directly or by referral to another clinician by:

(1) Fully and accurately completing all required specimen collection forms (physical or electronic copy) provided by the Department for this purpose;

(2) Collecting or arranging for the collection of specimens following state directions for collection provided;

(3) As soon as possible, but within 24 hours of collection, place or cause to be placed all specimens in the channel of transmittal to the designated prenatal birth defects screening laboratory.

(e) Blood collection forms and ~~blood collection and mailing~~ testing kits supplied by the Department or approved contractors shall not be copied, printed, reproduced, acquired, purchased, substituted, or distributed other than as specified for use ~~in~~ by the California Prenatal Screening Program administered by the Department.

(1) Prenatal licensed health facilities and blood draw stations shall obtain from the Department a sufficient supply of specimen collection tubes for prenatal screening for neural tube defects.

(f) When notified that a blood specimen is inadequate for testing, the clinician shall make a reasonable effort to have an adequate specimen obtained as soon as possible but not more than five

(5) days after such notification.

(g) For each ~~woman~~ individual in their care who participates in the California Prenatal Screening Program and who has a screen positive test result, as defined by the California Prenatal Screening Program, the clinician shall:

(1) Inform the ~~woman~~ individual that authorized follow-up services are available to that individual at State-approved Comprehensive and Satellite Prenatal Diagnosis Centers, and that the program participation fee(s) covers the authorized services.

(2) Report on the form provided by the Department for this purpose, within ~~30~~ 60 calendar days of the end of the pregnancy, the outcome of pregnancy and status of each fetus, or infant resulting therefrom.

(h) The test results shall be confidential so that such information shall only be released with the knowledge and specific written consent of the ~~woman~~ individual tested. Persons authorized by the Department to conduct and monitor screening and/or to provide and monitor follow-up services shall be provided information without necessity of specific written consent.

(i) Recognizing the strict gestational and time limits wherein prenatal detection of birth defects of the fetus is feasible, clinicians shall make every reasonable effort to schedule screening and differential diagnostic tests and procedures appropriately with respect to the gestational dates of the pregnant ~~woman~~ individual.

(j) Willful or repeated failure to comply with these regulations shall be referred by any person having knowledge of noncompliance to the appropriate licensing authority.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055, 125060, 125065 and 125070, Health Safety Code.

~~Section 6529. Rhesus (Rh) Hemolytic Disease.~~

~~—(a) Medical staffs of hospitals and physicians thereof shall in providing for the care of pregnant women determine that a blood specimen has been obtained for the determination of rhesus (Rh)~~

~~blood type or shall obtain or cause to be obtained a blood specimen within 24 hours of termination of pregnancy whether by delivery or by spontaneous or therapeutic abortion for this purpose.~~

~~—(b) All cases, or suspected cases of rhesus (Rh) hemolytic disease of the newborn, shall be reported to the Department. Every patient diagnosed in any licensed hospital as having such condition shall be reported by the hospital on the form provided by the Department for this purpose. The hospital shall notify the physician making the diagnosis that such a report has been filed.~~

~~Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.~~

~~Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125075, 125080, 125085 and 125090, Health and Safety Code.~~

Section 6531. Reporting of Neural Tube Defects.

(a) All cases of neural tube defect in a fetus or an infant under one year of age shall be reported to the Department.

(b) This report shall be made:

- (1) By the health facility in which the case is initially diagnosed;
- (2) By the physician making the initial diagnosis if the case is not diagnosed in a health facility;
- (3) Within 30 calendar days of the initial diagnosis;
- (4) On the form ~~to be~~ provided by the Department for this purpose, CDPH 4427 (~~0611/2015~~), incorporated by reference.

~~Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.~~

~~Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.~~

Section 6532. Reporting of Chromosomal Disorders.

(a) All cases of ~~Down syndrome or other~~ chromosomal defects in a fetus or an infant under one year of age shall be reported to the Department. Chromosomal defects shall mean any abnormality in structure or number of chromosomes.

(b) This report shall be made:

- (1) by the laboratory performing the chromosomal analysis or by the physician making the diagnosis;
- (2) within 30 calendar days of the initial diagnosis;
- (3) on a form ~~to be~~ provided by the Department for this purpose, CDPH 4427 (0611/2015), incorporated by reference.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

ARTICLE 4. CALIFORNIA PRENATAL SCREENING PROGRAM FEE COLLECTION

Section 6540. Program Participation Fees.

(a) The all-inclusive program participation fee for ~~maternal serum alpha fetoprotein and one or more additional markers used for prenatal~~ screening for ~~neural tube defects~~ NTD and Down Syndrome, shall be ~~\$221.60~~ \$85.00. The fee shall be paid to the Department by the ~~woman~~ individual being tested or by any third party which is legally responsible for ~~her~~ the individual's care, including any health care service plan, managed health care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan as defined or licensed in accordance with Health and Safety Code Section 1340, et seq. Uncollected fees shall be collected through the California Franchise Tax Board.

(b) The all-inclusive program participation fee for prenatal screening for autosomal trisomies shall be \$232.00. The fee shall be paid to the Department by the individual being tested or by any third party which is legally responsible for their care, including any health care service plan, managed health care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan as defined or licensed in accordance with Health and Safety Code Section 1340, et seq. Uncollected fees shall be collected through the California Franchise Tax Board.

(c) Prenatal health facilities and/or care providers may charge third party payers or patients for reasonable costs for blood specimen collection (venipuncture) and handling which should not exceed \$6.00.

Note: Authority cited: Sections 124977, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124996, 125000(b), 125000(f), 125001, 125050, 125060, 125065 and 131052, Health and Safety Code.

6540.1. Prepaid Group Practice Plan.

Health care providers which contract with a prepaid group practice health care service plan that annually has at least 20,000 births among its membership may provide, without contracting with the Department, any or all of the testing and counseling services required to be provided under this

Group, if the services meet quality standards established by the Department and the plan pays that portion of a fee established under ~~§~~section 6540 which is directly attributable to the Department's cost of administering the testing or counseling service and any required testing or counseling services provided by the state for plan members during the previous fiscal year. This option must be executed under terms of a written agreement with the Department. Payment by the plan shall be deemed to fulfill any obligation the provider or the provider's patient may have to the Department to pay a fee in connection with the testing or counseling service.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124975, 124977, 124980, 124990, 124996, 125000, 125001, 125050, 125055, 125060, 125065 and 125070, Health and Safety Code.

**ARTICLE 5. REQUIREMENTS FOR STATE-APPROVED COMPREHENSIVE AND SATELLITE
PRENATAL DIAGNOSIS CENTERS AND LABORATORIES TO PERFORM FOLLOW-UP
SERVICES**

**Section 6541. Requirements for Approval as a State-Approved Comprehensive Prenatal
Diagnosis Center.**

(a) A facility seeking approval as a State-approved Comprehensive Prenatal Diagnosis Center shall submit an application. Each application shall contain the following:

(1) An Application Coversheet that includes:

(A) The date the application was completed.

(B) The proposed name of the Center, organizational ownership, and any organizational unit and/or medical group affiliation.

(C) Center's physical location, the mailing address, and telephone and facsimile numbers.

(D) Genetic counseling services' physical location, the mailing address, and telephone and facsimile numbers.

(E) The full name, mailing address, telephone number, facsimile number, and email address of the individual(s) designated by the Applicant to be:

Director of the proposed Comprehensive Prenatal Diagnosis Center;

Prenatal Diagnosis Center Contact Person for mailings and distributions;

Back-up Prenatal Diagnosis Center Contact Person; and,

Quarterly Report Contact Person.

(F) The mailing address, telephone and facsimile numbers for mailing and distribution of Patient Result Mailers from the Department's Screening Information System.

(G) The name of the ultrasound practice, the ultrasound practice's American Institute of Ultrasound in Medicine or American College of Radiology accreditation number and expiration date, the physical location where ultrasounds are to be performed, the telephone number, and facsimile number. If amniocentesis and/or chorionic villus sampling procedures are to be performed

at a different location, the physical location, telephone number, and facsimile number of that location must also be provided.

(H) An affirmation that an Internal Continuous Quality Improvement Program description and a copy of the Ultrasound Accreditation Certificate are attached to the application.

(I) The name of the laboratory, or laboratories, authorized by the Department and to be utilized by the Applicant for the performance of prenatal cytogenomic and/or cytogenetic tests, the full name of the Director of each laboratory, the Clinical Laboratory Improvement Amendments (CLIA) certificate number, California Laboratory License number, the physical location, telephone number, and facsimile number of each laboratory, and the full names and California Laboratory License number for each Clinical Cytogeneticist employed by each facility.

(J) The full names of each of the following designated clinical staff members:

1. Clinical Geneticist(s).
2. Amniocentesis Practitioner(s), and Interim Approval Amniocentesis Practitioner(s), if applicable.
3. Transcervical Chorionic Villus Sampling Practitioner(s) and Interim Approval Transcervical Chorionic Villus Sampling Practitioner(s), if applicable.
4. Transabdominal Chorionic Villus Sampling Practitioner(s) and Interim Approval Transabdominal Chorionic Villus Sampling Practitioner(s), if applicable.
5. Consultative Sonologist(s).
6. Genetic Counselor(s).

(2) A Director's Agreement that includes:

(A) An affirmation by the designated Director that the statements contained in the application are true and complete to the best of the Applicant's knowledge, and that the designated Director will, as a condition of Comprehensive Prenatal

Diagnosis Center approval, comply with the provisions of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference, and:

1. Be responsible for the supervision and the quality of testing, counseling, and medical care provided by all clinical members of the State-approved Comprehensive Prenatal Diagnosis Center staff, including at any and all State-approved Satellite Prenatal Diagnosis Centers.
2. Ensure that all clients have appropriate, non-directive genetic counseling with thorough discussions of the risks of any prenatal diagnostic procedure or other testing to be performed, the chances of an abnormal outcome, and the available options if the results are abnormal.
3. Ensure that participation in prenatal diagnostic procedures or other testing by any pregnant woman is voluntary, and ensure a signed copy of any State-approved consent form is obtained from each patient prior to any prenatal diagnostic procedure or other testing.
4. Notify the Genetic Disease Screening Program within 10 calendar days of any case of maternal mortality ~~that could possibly be related to or associated with prenatal diagnosis.~~
5. Accept referrals for prenatal diagnostic procedures and for all pregnant women from State funded or administered programs.
6. Be responsible for overseeing the submission of quarterly reports, data for Adverse Outcome studies, and annual and other reports to the Department, as required by regulation and the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
7. Participate in and successfully complete any State provided or approved site visit, laboratory inspection, proficiency testing, and/or quality control program.
8. Ensure appropriate supervision of trainees or Genetic Counselors performing genetic counseling with a temporary license.
9. Ensure that an interdisciplinary meeting is held at least once every three months. This meeting shall include the State-approved Consultative

Sonologist(s), Amniocentesis Practitioner(s), Interim Approval Amniocentesis Practitioner(s), Transcervical Chorionic Villus Sampling Practitioner(s), Interim Approval Transcervical Chorionic Villus Sampling Practitioner(s), Transabdominal Chorionic Villus Sampling Practitioner(s), Interim Approval Transabdominal Chorionic Villus Sampling Practitioner(s), Genetic Counselor(s), and Clinical Geneticist(s).

10. Ensure that at all State-approved Satellite Prenatal Diagnosis Centers, the designated Clinical Geneticist conducts monthly meetings that include case review with the clinical staff who are assigned to the site.

11. Ensure that whenever chorionic villus sampling is offered, and either transabdominal or transcervical chorionic villus sampling is clinically contraindicated or unsuccessful, and the alternative prenatal diagnostic procedure is not available at the State-approved Comprehensive or any State-approved Satellite Prenatal Diagnosis Center, a referral is made to another State-approved Comprehensive or Satellite Prenatal Diagnosis Center.

12. Provide oversight to continuous quality improvement and work with staff to achieve improvement goals.

13. Ensure the Genetic Disease Screening Program of the Department is notified in writing within 10 calendar days of any changes (resignations, discharges and/or additions) in personnel, location, organizational ownership, any organizational unit and/or medical group affiliation, or any other items required for compliance with the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference. The notification shall state any changes which result in noncompliance with the requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022. Failure to state such changes will result in the Department's suspension of the State-approved Comprehensive or Satellite Prenatal Diagnosis Center.

14. Ensure a plan addressing such deficiency or noncompliance, pursuant to subsection (a)(2)(A)14 of this section, is developed and submitted to the Department within 30 calendar days upon receipt of such written notification.

15. Acknowledge that failure to submit a satisfactory plan to resolve deficiencies, or failure to satisfactorily resolve deficiencies within an additional 60 calendar days, if an extension of the suspension is granted, will result in approval being revoked for the State-approved Comprehensive or Satellite Prenatal Diagnosis Center.

(B) Be responsible for all information contained in the application, and acknowledging that the signed Agreement is a public document and that providing fraudulent information shall be cause for the Department to refuse or revoke approval of the State-approved Comprehensive and/or any Satellite Prenatal Diagnosis Center(s).

(C) The name of the proposed Comprehensive Prenatal Diagnosis Center.

(D) The names of any proposed Satellite Prenatal Diagnosis Centers.

(E) The designated Director's full name, title, signature and date of signing.

(3) Clinical Geneticist Statement(s). Each Clinical Geneticist shall submit a statement that must:

(A) Affirm the designated Clinical Geneticist will be responsible for the supervision of all professional services and for the evaluation of work performance by reviewing and signing off on all patient charts within 30 calendar days of the date of service.

(B) Affirm the designated Clinical Geneticist will be available to provide consultation in person to all families with abnormal or questionable results and will conduct monthly meetings with clinical staff who are assigned to the State-approved Comprehensive and/or Satellite Prenatal Diagnosis Center to include, but not be limited to, case review.

(C) Affirm the designated Clinical Geneticist is certified by the American Board of Medical Genetics and Genomics (ABMGG) in Clinical Genetics, or has Active

Candidate status for the next ABMGG examination in Clinical Genetics.

Documentation of Active Candidate status must be submitted to the Department.

The designated Clinical Geneticist must maintain Active Candidate status or otherwise meet ABMGG certification requirements in order to continue to provide clinical geneticist services.

(D) State the name and location of each proposed Comprehensive and/or Satellite Prenatal Diagnosis Center at which the designated Clinical Geneticist agrees to provide clinical geneticist services.

(E) Affirm the designated Clinical Geneticist has read the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference, and agrees to comply with the requirements in the document.

(F) Include the designated Clinical Geneticist's full name, signature, and date of signing.

(G) Include the designated Clinical Geneticist's California Medical License Number.

(H) Include the designated Director's full name, signature and date of signing, if the designated Clinical Geneticist is not the designated Director.

(4) Amniocentesis Practitioner Statement(s). Each Amniocentesis Practitioner Statement must:

(A) Indicate whether the practitioner has received prior approval from the Department as an Amniocentesis Practitioner or Interim Approval Amniocentesis Practitioner, or is applying for approval as a new Amniocentesis Practitioner or new Interim Approval Amniocentesis Practitioner.

(B) Affirm the designated practitioner has the training and experience with second trimester ultrasound-guided amniocentesis, obstetrical ultrasonography, and counseling for chromosomal, biochemical, and neural tube defects required for that practitioner category, as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

- (C) Affirm the designated practitioner will collect data for Adverse Outcome studies as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
- (D) State the name and location of each proposed Comprehensive and/or Satellite Prenatal Diagnosis Center at which the designated practitioner agrees to provide amniocentesis services.
- (E) Affirm the designated practitioner has read and agrees to comply with requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
- (F) Include the designated practitioner's full name, signature and date of signing.
- (G) Include the designated practitioner's California Medical License Number.
- (H) Include the designated Director's full name, signature and date of signing.
- (I) Include, for new Amniocentesis Practitioner or Interim Approval Amniocentesis Practitioner Applicants that have not received prior approval from the Department as an Amniocentesis Practitioner or Interim Approval Amniocentesis Practitioner:
1. Whether the Applicant is Board certified or is an Active Candidate for Board certification in Obstetrics and Gynecology, Clinical Genetics, Radiology, and/or in any other specialty.
 2. Whether or not the Applicant has completed a Fellowship in Maternal-Fetal Medicine or Reproductive Genetics.
 3. The total number of supervised second trimester amniocentesis procedures performed by the Applicant.
 4. The facility or facilities where supervised procedures were performed.
 5. The supervisor's or supervisors' name(s) and current address(es).
- (J) Include, for new Interim Approval Amniocentesis Practitioner Applicants that have not received prior approval from the Department as an Interim Approval Amniocentesis Practitioner, and for existing Interim Approval Amniocentesis Practitioners being added to the staff:
1. The Applicant's email address.
 2. The Applicant's fellowship institution and type of training program.

3. Whether the Applicant is currently in, or the year of completion of, a Maternal-Fetal Medicine or equivalent specialized training program.
4. A list of the Applicant's designated supervisor(s) at all proposed Comprehensive and/or Satellite Prenatal Diagnosis Center sites. The designated supervising practitioner(s) must meet and adhere to the requirements outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
5. Documentation from each designated supervising practitioner agreeing to adhere to the supervision requirements outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference, while the Interim Approval Amniocentesis Practitioner is performing second trimester amniocenteses. If the Interim Approval Amniocentesis Practitioner Applicant has multiple designated supervisors, one letter from a State-approved practitioner who is acknowledged to be a primary supervisor, and listing all designated supervising practitioners, may be included.
6. An affirmation from the Interim Approval Amniocentesis Practitioner Applicant that the 15 second trimester amniocentesis procedures following interim approval shall be performed with a supervising State-approved Amniocentesis Practitioner present in the room and immediately available to the practitioner during the procedures; and that a log with a patient identifier, the indication for the procedure, the date of the procedure, the gestational age at the time of the procedure, the number of fetuses, the State-approved Comprehensive or Satellite Prenatal Diagnosis Center site number, and the name of the supervising practitioner must be maintained and submitted to the Department every six months and upon completion of the procedures.
7. An affirmation that the Interim Approval Amniocentesis Practitioner Applicant agrees to comply with the above requirements, and understands that noncompliance will result in the withdrawal of approval.

8. The Interim Approval Amniocentesis Practitioner Applicant's signature and date of signing.

(5) For an Applicant organization applying for approval to provide optional transcervical chorionic villus sampling services, a Transcervical Chorionic Villus Sampling Practitioner Statement(s) must be included. Each Transcervical Chorionic Villus Sampling Practitioner Statement must:

(A) Indicate whether the practitioner has received, or is applying for, approval from the Department as a Transcervical Chorionic Villus Sampling Practitioner or Interim Approval Transcervical Chorionic Villus Sampling Practitioner.

(B) Affirm the designated practitioner has the training and experience with first trimester transcervical chorionic villus sampling required for that practitioner category, as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(C) Affirm the designated practitioner will collect data for Adverse Outcome studies as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(D) State the name and location of each proposed Comprehensive and/or Satellite Prenatal Diagnosis Center where the designated practitioner agrees to provide transcervical chorionic villus sampling services.

(E) Affirm the designated practitioner has read and agrees to comply with the requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(F) Include the designated practitioner's signature, full name, and date of signature.

(G) Include the designated practitioner's California Medical License Number.

(H) Include the designated Director's signature, full name, and date of signature.

(I) Include for new Applicants that have not received prior approval from the Department as Transcervical Chorionic Villus Sampling Practitioners or Interim Approval Transcervical Chorionic Villus Sampling Practitioners:

1. Whether the Applicant is Board certified or is an Active Candidate for Board certification by the American Board of Obstetrics and Gynecology (ABOG).
2. If the Applicant is experienced in ultrasound guided amniocentesis.
3. The total number of first trimester transcervical chorionic villus sampling procedures performed on women not continuing their pregnancies, with the dates between which such procedures were performed.
4. The total number of supervised first trimester transcervical chorionic villus sampling procedures performed on women continuing their pregnancies, with the dates between which such procedures were performed.
5. The facility or facilities where supervised transcervical chorionic villus sampling procedures were performed.
6. The supervisor's or supervisors' name(s) and current address(es).

(J) Include, for Interim Approval Transcervical Chorionic Villus Sampling Practitioner Applicants that have not received prior approval from the Department as an Interim Approval Transcervical Chorionic Villus Sampling Practitioner, and for existing Interim Approval Transcervical Chorionic Villus Sampling Practitioners being added to the staff:

1. The Applicant's email address.
2. The Applicant's Fellowship Institution and type of training program.
3. Whether the Applicant is currently in a Maternal-Fetal Medicine or equivalent specialized training program, or the year of completion of the Maternal-Fetal Medicine or equivalent specialized training program.
4. A list of the Applicant's designated supervisor(s) at all proposed Comprehensive and/or Satellite Prenatal Diagnosis Centers. The designated supervising practitioner(s) must meet the requirements outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

5. Documentation from each designated supervising practitioner agreeing to adhere to the supervision requirements outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference, while the Interim Approval Transcervical Chorionic Villus Sampling Practitioner is performing first trimester transcervical chorionic villus sampling. If the Interim Approval Transcervical Chorionic Villus Sampling Practitioner Applicant has multiple supervisors, one letter from a State-approved practitioner who is acknowledged to be a primary supervisor, and listing all designated supervising practitioners, may be included.

6. An affirmation from the Interim Approval Transcervical Chorionic Villus Sampling Practitioner Applicant that the 13 first trimester transcervical chorionic villus sampling procedures following interim approval shall be performed with a supervising State-approved Transcervical Chorionic Villus Sampling Practitioner in the room and immediately available to the practitioner during the procedures; and that a log with a patient identifier, the indication for the procedure, the date of the procedure, the gestational age at the time of the procedure, the number of fetuses, the State-approved Comprehensive or Satellite Prenatal Diagnosis Center site number, and the name of the supervising practitioner must be maintained and submitted to the Department every six (6) months and upon completion of the procedures.

7. An affirmation that the Interim Approval Transcervical Chorionic Villus Sampling Practitioner Applicant agrees to comply with the above requirements, and understands that noncompliance will result in the withdrawal of approval.

8. The Interim Approval Transcervical Chorionic Villus Sampling Practitioner Applicant's signature and date of signing.

(6) For an Applicant organization applying for approval to provide optional transabdominal chorionic villus sampling services, a Transabdominal Chorionic Villus

Sampling Practitioner Statement(s) must be included. Each Transabdominal Chorionic Villus Sampling Practitioner Statement must:

- (A) Indicate whether the practitioner has received prior, or is applying for, approval from the Department as a Transabdominal Chorionic Villus Sampling Practitioner or Interim Approval Transabdominal Chorionic Villus Sampling Practitioner.
- (B) Affirm the designated practitioner has the training and experience with transabdominal chorionic villus sampling required for that practitioner category, as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
- (C) Affirm the designated practitioner will collect data for Adverse Outcome studies as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
- (D) State the name and location of each Comprehensive and/or Satellite Prenatal Diagnosis Center site at which the designated practitioner agrees to provide transabdominal chorionic villus sampling services.
- (E) Affirm the designated practitioner has read and agrees to comply with the requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
- (F) Include the designated practitioner's signature, full name, and date of signing.
- (G) Include the designated practitioner's California Medical License Number.
- (H) Include the designated Director's signature, full name, and date of signing.
- (I) Include, for new Applicants that have not received prior approval from the Department as a Transabdominal Chorionic Villus Sampling Practitioner or Interim Approval Transabdominal Chorionic Villus Sampling Practitioner:
 - 1. Whether the Applicant is certified or is an active candidate for certification by the ~~American Board of Obstetrics and Gynecology~~ ABOG.
 - 2. Whether or not the Applicant is approved by the Department as an Amniocentesis Practitioner, or is experienced in amniocentesis.

3. Whether the Applicant is approved by, or is concurrently applying for approval by, the Department as a Transcervical Chorionic Villus Sampling Practitioner.
4. The total number of first trimester transabdominal chorionic villus sampling procedures performed on women not continuing their pregnancies, with the dates between which such procedures were performed.
5. The total number of supervised first trimester transabdominal chorionic villus sampling procedures performed on women continuing their pregnancies, with the dates between which such procedures were performed.
6. The facility or facilities where supervised first trimester transabdominal chorionic villus sampling procedures were performed.
7. The supervisor's or supervisors' name(s) and current address(es).

(J) Include, for new Interim Approval Transabdominal Chorionic Villus Sampling Practitioner Applicants that have not received prior approval from the Department as an Interim Approval Transabdominal Chorionic Villus Sampling Practitioner, and for existing Interim Approval Transabdominal Chorionic Villus Sampling Practitioner being added to the staff:

1. The Applicant's email address.
2. The Applicant's Fellowship Institution and type of training program.
3. Whether the Applicant is currently in, or the year of completion of, a Maternal-Fetal Medicine or equivalent specialized training program.
4. A list of the Applicant's designated supervisor(s) at all Prenatal Diagnosis Center sites. The designated supervising practitioner(s) must meet the requirements outlined in the Prenatal Diagnosis Center Standards and Definitions 20182022, incorporated by reference.
5. Documentation from each designated supervising practitioner agreeing to adhere to the supervision requirements outlined in the Prenatal Diagnosis Center Standards and Definitions 20182022, incorporated by

reference, while the Interim Approval Transabdominal Chorionic Villus Sampling is performing first trimester chorionic villus sampling. If the Interim Approval Transabdominal Chorionic Villus Sampling Practitioner Applicant has multiple supervisors, one letter from a State-approved practitioner who is acknowledged to be a primary supervisor, and listing all designated supervising practitioners, may be included.

6. An affirmation from the Interim Approval Transabdominal Chorionic Villus Sampling Practitioner Applicant that the 13 first trimester transabdominal chorionic villus sampling procedures following interim approval shall be performed with a supervising State-approved Transabdominal Chorionic Villus Sampling Practitioner in the room and immediately available to the practitioner during the procedures; and that a log with a patient identifier, the indication for the procedure, the date of the procedure, the gestational age at the time of the procedure, the number of fetuses, the Prenatal Diagnosis Center site number, and the name of the supervising practitioner must be maintained and submitted to the Department every six months and upon completion of the procedures.

7. An affirmation that the Interim Approval Transabdominal Chorionic Villus Sampling Practitioner Applicant agrees to comply with the above requirements, and understands that noncompliance will result in the withdrawal of approval.

8. The Interim Approval Transabdominal Chorionic Villus Sampling Practitioner Applicant's signature and date of signing.

(7) A Consultative Sonologist Practitioner Statement(s). Each Consultative Sonologist Practitioner Statement must:

(A) Indicate whether the practitioner has received prior approval from the Department as a Consultative Sonologist Practitioner, or is applying for approval as a new Consultative Sonologist Practitioner.

(B) Affirm the designated practitioner has had training and is experienced in the ultrasonographic detection of fetal abnormalities as outlined in the Prenatal

Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(C) Affirm the designated practitioner is part of a practice that is accredited by the American College of Radiology or the American Institute of Ultrasound in Medicine, and that the accreditation covers the proposed Comprehensive and/or Satellite Prenatal Diagnosis Centers listed in the Statement.

(D) State the name and location of each proposed Comprehensive and/or Satellite Prenatal Diagnosis Center at which the designated practitioner agrees to provide consultative ultrasonography services.

(E) Affirm the designated practitioner has read and agrees to comply with the requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(F) Include the designated practitioner's signature, full name, and date of signing.

(G) Include the designated practitioner's California Medical License Number.

(H) Include the designated Director's signature, full name, and date of signing.

(I) Indicate whether the designated practitioner is covered by an Ultrasound Practice Accreditation by the American College of Radiology or the American Institute of Ultrasound in Medicine, and include the Accreditation Number.

(J) Include, for new Consultative Sonologist Practitioner Applicants that have not received prior approval from the Department as a Consultative Sonologist Practitioner:

1. Whether the Applicant is Board certified or an Active Candidate for Board certification in Obstetrics and Gynecology, Clinical Genetics, Radiology, and/or in any other specialty.
2. A copy of the Applicant's curriculum vitae.
3. Whether or not the Applicant has completed a Fellowship in Maternal-Fetal Medicine in a facility that performs at least 2,000 second trimester fetal ultrasound exams each year, and where the fellowship was completed.

4. Whether or not the Applicant has completed a Fellowship in Clinical Genetics with an emphasis upon fetal medicine in a facility that performs at least 2,000 second trimester fetal ultrasound exams each year, and where the fellowship was completed.
5. Whether or not the Applicant has completed a Fellowship in diagnostic radiology, body imaging, or the equivalent with an emphasis upon fetal medicine in a facility that performs at least 2,000 second trimester fetal ultrasound exams per year, and where the fellowship was completed.
6. Whether or not the Applicant has completed training, either as supplemental training or part of a fellowship, at a facility that performs at least 2,000 second trimester fetal ultrasound exams a year, and the name of the facility where any such training was completed. The training must have included at least three (3) months of targeted fetal ultrasound examinations that involve high-risk obstetric imaging and must include basic physics, techniques, performance, and interpretation followed by three (3) months of proctoring by a qualified consultative sonologist.
7. The number of detailed second trimester ultrasound examinations performed by the Applicant specifically for the detection of fetal abnormalities. Indications may include twins, early growth delay, oligohydramnios, polyhydramnios, abnormality observed at another facility, history of genetically transmitted disease, insulin dependent diabetes, family history of malformation and advanced maternal age. Detailed second trimester ultrasound examinations must have included: fetal number, fetal presentation, documentation of fetal life, placental localization, amniotic fluid volume, gestational dating, detection and evaluation of maternal pelvic mass, and a survey of fetal anatomy for malformations.

- (8) A Genetic Counselor Statement(s). Each Genetic Counselor Statement must:
- (A) Affirm the designated Genetic Counselor has a Genetic Counselor License or temporary Genetic Counselor License issued by the Department.

- (B) State the name and location of each proposed Comprehensive and/or Satellite Prenatal Diagnosis Center at which the designated Genetic Counselor agrees to provide genetic counseling services.
 - (C) Affirm the designated Genetic Counselor has read and agrees to comply with the requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
 - (D) Include the designated Genetic Counselor's signature, full name, and date of signing.
 - (E) Include the designated Genetic Counselor's California License Number.
 - (F) Include the designated Director's signature, full name, and date of signing.
- (9) A Laboratory Director Statement from each laboratory approved by the Department to perform follow-up services and to be utilized by the Applicant for prenatal cytogenomic and/or cytogenetic tests. Each Laboratory Director Statement must:
- (A) Affirm the Laboratory Director is a physician or holds a doctorate degree, has training and experience as a Clinical Cytogeneticist directing a prenatal diagnosis cytogenetics laboratory, and is certified by the American Board of Medical Genetics and Genomics or Canadian College of Medical Genetics in Clinical Cytogenetics.
 - (B) State the name and address of the laboratory.
 - (C) Include the CLIA certificate number and the California Laboratory License number of the laboratory.
 - (D) Indicate the cytogenomic and/or cytogenetic tests the designated Laboratory Director is agreeing to provide for the proposed Comprehensive and/or Satellite Prenatal Diagnosis Centers listed.
 - (E) State the names of each proposed Comprehensive and/or Satellite Prenatal Diagnosis Center for which the Laboratory Director agrees to provide cytogenomic and/or cytogenetic tests.
 - (F) Affirm the Laboratory Director has read and agrees to comply with the requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

- (G) Include the Laboratory Director's signature, full name, and date of signing.
- (H) Include the Laboratory Director's California License Number.
- (I) Include the signature, date of signing and full name of the designated Director of the proposed Comprehensive Prenatal Diagnosis Center.

~~(10) A Cell-free DNA Screening Provider or Laboratory Agreement for each Cell-free DNA Screening provider or laboratory to be utilized by the Applicant for Cell-free DNA Screening. Each Cell-free DNA Screening Provider or Laboratory Agreement must:~~

- ~~(A) Include the name of the proposed Comprehensive Prenatal Diagnosis Center and the name of the Cell-free DNA Screening provider or laboratory.~~
- ~~(B) Specify the Cell-free DNA Screening laboratory where tests will be performed, and the physical location, CLIA certificate number, and California Laboratory License number.~~
- ~~(C) Affirm the proposed Comprehensive Prenatal Diagnosis Center is establishing a formal agreement with the Cell-free DNA Screening provider or laboratory, and that:~~

- ~~1. The Cell-free DNA Screening provider or laboratory shall provide a mechanism to the proposed Comprehensive and Satellite Prenatal Diagnosis Centers for identifying cell-free DNA screening specimens from authorized California Prenatal Screening Program referrals.~~
- ~~2. The Cell-free DNA Screening provider or laboratory shall report the cell-free DNA screening result to the medical professional of the proposed Comprehensive or Satellite Prenatal Diagnosis Center who ordered the screening.~~
- ~~3. The Cell-free DNA Screening provider or laboratory shall accept payment from the proposed Comprehensive Prenatal Diagnosis Center as payment in full for any cell-free DNA screening service authorized and successfully performed for a California Prenatal Screening Program patient of the proposed Comprehensive or Satellite Prenatal Diagnosis Center(s).~~

~~4. The proposed Comprehensive Prenatal Diagnosis Center shall accept cell-free DNA screening reimbursement from the Department as payment in full for any cell-free DNA screening laboratory service authorized and successfully performed for a California Prenatal Screening Program patient of the proposed Comprehensive or Satellite Prenatal Diagnosis Center, and shall not charge the patient or the patient's insurance.~~

~~5. The designated Director of the proposed Comprehensive Prenatal Diagnosis Center shall assume responsibility for compliance with the cell-free DNA screening sample collection and follow-up services.~~

~~(D) List the name of the proposed Comprehensive Prenatal Diagnosis Center and the names of any proposed Satellite Prenatal Diagnosis Centers for which the designated Cell-free DNA Screening provider or laboratory will provide cell-free DNA screening to authorized California Prenatal Screening Program referrals.~~

~~(E) Include the signature, date of signing, and full name of the designated Director of the proposed Comprehensive Prenatal Diagnosis Center.~~

~~(F) Include the full name, signature and date of signing by the Administrator or other appropriate representative of the Cell-free DNA Screening provider or laboratory.~~

(140) A Clinical Schedule and Staff Coverage Statement that indicates the date completed, and, for each proposed Comprehensive and Satellite Prenatal Diagnosis Center:

(A) The name of the proposed Comprehensive or Satellite Prenatal Diagnosis Center.

(B) The telephone number to call for appointments.

(C) The name of a designated Appointment Scheduler.

(D) A secured facsimile number.

(E) How often is the clinic held.

(F) The name of each designated Clinical Geneticist, Amniocentesis Practitioner, Interim Approval Amniocentesis Practitioner, Transcervical Chorionic Villus

Sampling Practitioner, Interim Approval Transcervical Chorionic Villus Sampling Practitioner, Transabdominal Chorionic Villus Sampling Practitioner, Interim Approval Transabdominal Chorionic Villus Sampling Practitioner, Consultative Sonologist, and Genetic Counselor, and the days and times of the week they will provide services.

(121) An Internal Continuous Quality Improvement Program description.

(132) A copy of the Ultrasound Accreditation Certificate.

(b) If an incomplete application is received, the Applicant shall be notified and have 30 calendar days from the date of notification by the Department to complete the application process, including the submission of support documentation.

(c) Applicant will be notified by the Department of the receipt of a complete application.

(d) Following receipt and review of a completed application, the Department will conduct a site visit.

(e) If there are findings of deficiencies during the Department's site visit, the Applicant will be notified of the findings and have 30 calendar days following notification to successfully comply with or resolve any findings.

(f) Failure to meet any requirements of this section shall cause the Department to consider the application withdrawn. The Applicant shall remain eligible to reapply for authorization as a State-approved Comprehensive Prenatal Diagnosis Center.

(g) If there are no findings of deficiency during the site visit, or if any findings are successfully complied with or resolved, the Department shall notify the Applicant of approval to enter into a contract with the Department as a State-approved Comprehensive Prenatal Diagnosis Center.

(h) Upon execution of the contract, the applicant shall be notified. Approval to provide authorized follow up services may only be offered to California Prenatal Screening Program referrals upon execution of a contract with the department. At least seven (7) calendar days within the date of notification the following information shall be submitted by the applicant:

(1) The Applicant must confirm the information provided in the original application remains unchanged. If there are any changes in location or the personnel, the applicant must submit changes by submitting the documentation as stated in section 6541 (a) (1) through (13) of this Article.

(2) The Applicant must confirm in writing the full names and emails of the staff members designated to be responsible for each of the following functions in the Department's Screening Information System (SIS), with a statement of whether each person has or needs access to the Department's Screening Information System:

(A) Appointment Scheduler(s).

(B) Patient Service Reports Contact(s).

(C) Invoice Liaison(s).

(3) If a staff member is designated to perform multiple functions, that person's name should be listed under each function. The names, emails, and functions of any additional staff members requiring access to the Screening Information System must also be provided. Each staff member requiring access to the Screening Information System must sign and submit a copy of the Screening Information System Oath of Confidentiality.

(i) Failure to provide written confirmation that there are no changes from the information on the application within 30 calendar days of the notification shall cause the Department to consider the application withdrawn.

(j) Upon written confirmation that there are no changes from the application or to the names, emails, and Oath of Confidentiality of the staff members requiring access to the Department's Screening Information System (SIS), the Department shall notify the applicant of the date from which they may offer authorized follow up services to California Prenatal Screening Program referrals. The approval shall be valid only in the location stated and with the personnel listed, and shall be subject to any conditions stated by the Department.

(k) If the State-approved Comprehensive Prenatal Diagnosis Center is not operational and able to schedule California Prenatal Screening Program referrals for authorized follow-up services within 30 calendar days following the date of the approval by the Department, approval as a State-approved Comprehensive Prenatal Diagnosis Center will be withdrawn by the Department.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6542. Requirements for Approval as a State-Approved Satellite Prenatal Diagnosis Center.

(a) A State-approved Comprehensive Prenatal Diagnosis Center, or Comprehensive Prenatal Diagnosis Center Applicant, seeking Departmental approval to operate a State-approved Satellite Prenatal Diagnosis Center(s) shall submit an application to the Department. Each application shall contain the following to demonstrate the proposed Satellite Prenatal Diagnosis Center(s) has the capacity to meet the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference:

- (1) An Application Coversheet for each proposed Satellite Prenatal Diagnosis Center site that includes:
 - (A) The date the application was completed.
 - (B) The name of the State-Approved Comprehensive Prenatal Diagnosis Center, or Comprehensive Prenatal Diagnosis Center Applicant.
 - (C) Name of the Prenatal Diagnosis Center Director.
 - (D) The proposed name of the Satellite Prenatal Diagnosis Center, its organizational ownership, and any organizational unit and/or medical group affiliation.
 - (E) The physical location, the mailing address, telephone and facsimile numbers of the site of the proposed Satellite Prenatal Diagnosis Center.
 - (F) The physical location, the mailing address, telephone and facsimile numbers where genetic counseling services are to be provided, if different from the above address.
 - (G) The name of the ultrasound practice, the ultrasound practice's American Institute of Ultrasound in Medicine or American College of Radiology accreditation number and expiration date, the physical location where ultrasounds are to be performed, the telephone number, and facsimile number. If amniocentesis and/or chorionic villus sampling procedures are to be performed

at a different location, the physical location, telephone number, and facsimile number of that location must also be provided.

(H) An affirmation that an Internal Continuous Quality Improvement Program description and a copy of the Ultrasound Accreditation Certificate are attached to the application.

(I) The following information for each laboratory approved by the Department for follow-up services and to be utilized by the proposed Satellite Prenatal Diagnosis Center for cytogenomic and/or cytogenetic tests:

1. The full name of the Laboratory Director.
2. The Clinical Laboratory Improvement Amendments (CLIA) certificate number.
3. The California Laboratory License number.
4. The physical location, telephone and facsimile numbers.
5. The full names and California License numbers for each of the Clinical Cytogeneticists employed by each facility.

(J) The full names of each of the following designated Clinical Staff Members:

1. Clinical Geneticist(s).
2. Amniocentesis Practitioner(s), and Interim Approval Amniocentesis Practitioner(s), if applicable.
3. Transcervical Chorionic Villus Sampling Practitioner(s) and Interim Approval Transcervical Chorionic Villus Sampling Practitioner(s), if applicable.
4. Transabdominal Chorionic Villus Sampling Practitioner(s) and Interim Approval Transabdominal Chorionic Villus Sampling Practitioner(s), if applicable.
5. Consultative Sonologist(s).
6. Genetic Counselor(s).

(2) The information required for Comprehensive Prenatal Diagnosis Center Applicants outlined in section 6541 (a) (1) through (13) of this Article. Information should be

submitted for all Centers for which approval is sought, including all Satellite Prenatal Diagnosis Centers.

(3) An Agreement between a State-approved Comprehensive Prenatal Diagnosis Center or Comprehensive Prenatal Diagnosis Center Applicant and each proposed Satellite Prenatal Diagnosis Center. Each Agreement must:

(A) Include the names of the proposed Satellite Prenatal Diagnosis Center site and the Comprehensive Prenatal Diagnosis Center.

(B) Affirm that the proposed Satellite Prenatal Diagnosis Center site has a formal agreement with the Comprehensive Prenatal Diagnosis Center.

(C) Affirm that the State-approved Comprehensive Prenatal Diagnosis Center will be responsible for compliance with the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference, including the provision of quality diagnostic procedures, genetic counseling, ultrasound and prenatal specimen testing by a laboratory approved by the Department to perform follow-up services.

(D) Include the name and location of the laboratory to be utilized by the proposed Satellite Prenatal Diagnosis Center to perform cytogenomic and/or cytogenetic tests.

(E) Affirm that if services are to be provided in a licensed hospital, designated practitioners at the proposed Satellite Prenatal Diagnosis Center have staff privileges and/or are authorized to use inpatient or outpatient hospital-operated facilities.

(F) Include the full name, signature and date of signing by the Administrator of the proposed Satellite Prenatal Diagnosis Center, or name of other appropriate representative.

(G) Include the full name, signature, and date of signing by the Director or designated Director of the Comprehensive Prenatal Diagnosis Center.

(b) If an incomplete application is received, the Applicant shall be notified and have 30 calendar days from the date of notification by the Department to complete the application process, including the submission of support documentation.

- (c) Applicant will be notified by the Department of the receipt of a complete application.
- (d) Following receipt and review of a completed application, the Department will conduct a site visit.
- (e) If there are findings of deficiencies during the Department's site visit, the Applicant will be notified of the findings and have 30 calendar days following notification to successfully comply with or resolve any findings.
- (f) Failure to meet any requirements of this Section will cause the Department to consider the application withdrawn. The Applicant remains eligible to reapply for authorization of the State-approved Satellite Prenatal Diagnosis Center.
- (g) If there are no findings during the site visit, or if any findings are successfully complied with or resolved, the Department shall request that the following information be submitted by the applicant within seven (7) calendar days of the date of the notification:
- (1) The Applicant must confirm the information provided in the original application remains unchanged. If there are any changes in location or the personnel, the applicant must submit changes by submitting the documentation as stated in section 6541 (a) (1) through (13) of this Article.
 - (2) The Applicant must confirm in writing the full names and emails of the staff members designated to be responsible for each of the following functions in the Department's Screening Information System (SIS), with a statement of whether each person has or needs access to the Department's Screening Information System:
 - (A) Appointment Scheduler(s).
 - (B) Patient Service Reports Contact(s).
 - (C) Invoice Liaison(s).
 - (3) If a staff member is designated to perform multiple functions, that person's name should be listed under each function. The names, emails, and functions of any additional staff members requiring access to the Screening Information System must also be provided. Each staff member requiring access to the Screening Information System must sign and submit a copy of the Screening Information System Oath of Confidentiality.
- (h) Failure to provide confirmation within 30 calendar days of the notification shall cause the Department to consider the application withdrawn.

(i) Upon written confirmation that there are no changes from the application or to the names, emails, and Oath of Confidentiality of the staff members requiring access to the Department's Screening Information System (SIS), the Department shall notify the applicant of the date from which they may offer authorized follow up services to California Prenatal Screening Program referrals. The approval shall be valid only in the location stated and with the personnel listed, and shall be subject to any conditions stated by the Department.

(j) If the State-approved Satellite Prenatal Diagnosis Center is not operational and able to schedule California Prenatal Screening Program referrals for authorized follow-up services within 30 calendar days following the date of the approval by the Department, approval as a State-approved Satellite Prenatal Diagnosis Center will be withdrawn by the Department.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6543. Requirements for Continued Approval as a State-Approved Comprehensive or Satellite Prenatal Diagnosis Center.

(a) Continued approval as a State-Approved Comprehensive Prenatal Diagnosis Center or State-Approved Satellite Prenatal Diagnosis Center is dependent on compliance with the regulations set forth herein and the provisions of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(b) Any changes in personnel or in the location(s) where services are provided may render the approval void. If there are any changes in the location(s) where services are provided, the staffing, or providers of follow-up services, the Director of the State-approved Comprehensive Prenatal Diagnosis Center must notify the Department within 10 calendar days and submit documentation of any new clinical staff or providers of follow-up services for approval, verifying they meet the requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference. If there are no findings of deficiencies, or if any findings of deficiencies are successfully complied with or resolved, the Department shall notify the Applicant of continued approval of the State-approved Comprehensive Prenatal Diagnosis Center and any Satellite Prenatal Diagnosis

Centers. The approval shall be valid only in the location(s) stated and with the personnel listed, and shall be subject to any conditions stated in the Department notification.

(c) Before the end of each calendar year, the Department will provide to the State-approved Comprehensive Prenatal Diagnosis Center a list of site names, addresses, phone and facsimile numbers, any approval conditions, and the clinical staff approved to provide services at the State-Approved Comprehensive Prenatal Diagnosis Center and any State-Approved Satellite Prenatal Diagnosis Centers. The State-approved Comprehensive Prenatal Diagnosis Center must review the conditions of approval, submit requested information, and review the personnel listings for accuracy. Within 30 calendar days after receiving this information from the Department, the State-approved Comprehensive Prenatal Diagnosis Center must submit the following documentation:

(1) An Annual Reporting Coversheet that includes:

(A) The name of the person submitting the documentation.

(B) The date the submission was completed.

(C) For the State-approved Comprehensive Prenatal Diagnosis Center site, the following clinical services information:

1. The name of the State-approved Comprehensive Prenatal Diagnosis Center.
2. The physical location where genetic counseling services are provided, and the telephone number and facsimile number of that location.
3. The name of the ultrasound practice, the American Institute of Ultrasound in Medicine/American College of Radiology accreditation number and expiration date, and the physical location, telephone number, and facsimile number of the location where ultrasound services are performed.
4. The number of the following from November 1 of the prior year to October 31 of the current year, including California Prenatal Screening Program referrals:
 - i. Amniocentesis procedures performed.
 - ii. Chorionic villus sampling procedures performed.
 - iii. Women seen for prenatal genetic services. (If a State-approved Comprehensive Prenatal Diagnosis Center has not seen the minimum annual volume of 100 patients for genetic counseling, a letter of

justification for maintaining approval must be submitted to the Department.)

5. The full name, mailing address, telephone and facsimile numbers, and email address of the following personnel at the State-approved Comprehensive Prenatal Diagnosis Center:

- i. Director.
- ii. Contact Person.
- iii. Back-up Contact Person.

6. For each laboratory authorized by the Department and utilized by the State-approved Comprehensive Prenatal Diagnosis Center for cytogenomic and/or cytogenetic tests, provide the following:

- i. Laboratory name.
- ii. Full name of the Laboratory Director.
- iii. California License number for Laboratory Director.
- iv. Physical location.
- v. Full names for each of the Clinical Cytogeneticists employed.
- vi. California License number for each of the Clinical Cytogeneticists employed.

(D) For each State-approved Satellite Prenatal Diagnosis Center, the following clinical services information:

1. The name and Department-assigned code of the State-approved Satellite Prenatal Diagnosis Center.
2. The physical location where genetic counseling services are provided, and the telephone number and facsimile number of that location.
3. The name of the ultrasound practice, and the American Institute of Ultrasound in Medicine/American College of Radiology accreditation number and expiration date, and the physical location where ultrasound services are performed.
4. The number of the following from November 1 of the prior year to October 31 of the current year, including California Prenatal Screening Program referrals:
 - i. Amniocentesis procedures performed.

- ii. Chorionic villus sampling procedures performed.
- iii. Women seen for prenatal genetic services. (If a State-approved Satellite Prenatal Diagnosis Center has not seen the minimum annual volume of 100 patients for genetic counseling, a letter of justification for maintaining approval must be submitted to the Department.)

(2) Statistics for each approved Amniocentesis Practitioner, Interim Approval Amniocentesis Practitioner, Transabdominal Chorionic Villus Sampling Practitioner, Interim Approval Transabdominal Chorionic Villus Sampling Practitioner, Transcervical Chorionic Villus Sampling Practitioner, Interim Approval Transcervical Chorionic Villus Sampling Practitioner, and Consultative Sonologist for procedures performed from November 1 of the prior year to October 31 of the current year, including California Prenatal Screening Program referrals. For Amniocentesis Practitioners and Interim Approval Amniocentesis Practitioners, only procedures performed prior to 24 weeks gestational age should be reported. For Consultative Sonologists, only examinations performed after 15 weeks gestational age should be reported. Procedures included should be restricted to those performed at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers, unless a Practitioner has not performed enough procedures to meet the minimum requirements of the Prenatal Diagnosis Centers Standards and Definitions ~~2018~~2022, incorporated by reference, but performs procedures at other non-State-approved sites. Those procedures may be reported but should be listed separately from the procedures performed at the State-approved Comprehensive and any Satellite Prenatal Diagnosis Centers, and a note of this exception should be made when reporting.

(3) Number of cytogenomic and cytogenetic tests performed by each laboratory approved by the Department to perform follow-up services and ordered by the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers, including for California Prenatal Screening Program referrals, from November 1 of the prior year to October 31 of the current year.

(4) A Director's agreement containing the information outlined in section 6541 (a)(2) of this Article.

(5) A Clinical Staff Schedule containing the information outlined in section 6541 (a)(11) of this Article.

(d) If documentation submitted to meet the requirements of subsection (c) is incomplete, the State-approved Comprehensive Prenatal Diagnosis Center shall have seven (7) calendar days to complete the reporting process, including the submission of support documentation, from the date of notification by the Department that additional information is required.

(e) If there are findings of deficiencies from documentation submitted to meet the requirements of subsection (c), the State-approved Comprehensive Prenatal Diagnosis Center will be notified of the findings and shall have 30 calendar days from the date of notification by the Department to successfully comply with or resolve any findings of deficiencies.

(f) Failure to meet any requirements of this section will cause the Department to consider suspension or revocation of approval.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6544. Suspension and Revocation of Approval as a State-Approved Comprehensive or Satellite Prenatal Diagnosis Center.

Approval as a State-approved Comprehensive or Satellite Prenatal Diagnosis Center may be suspended or revoked by the Department if the State-approved Comprehensive or Satellite Prenatal Diagnosis Center:

(a) Knowingly makes a false statement of fact or omits to state a fact on an application or renewal application that would have resulted in the denial of approval.

(b) Fails to comply with the provisions of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(c) Fails to operate and furnish services in compliance with all other applicable state laws, regulations, and local ordinances.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6545. Process to Request Review Following Denial or Revocation of Approval as a State-Approved Comprehensive or Satellite Prenatal Diagnosis Center.

Any person aggrieved by the Department's decision to deny, revoke, or refuse to renew approval of a State-Approved Comprehensive or Satellite Prenatal Diagnosis Center, may request a hearing.

(a) A request for a hearing must be made in writing within 30 days of the date that the Department's notification of denial or revocation was issued.

(b) The request for hearing must be made in writing to the address found on the Department's website for the Chief, ~~Program Standards and Quality Assurance Branch~~, Genetic Disease Screening Program in the California Department of Public Health, and must clearly state the reasons for the request.

(c) Hearings shall be conducted pursuant to Health and Safety Code section 131071.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055, 125065 and 131071, Health and Safety Code.

Section 6546. Requirements for Laboratories to be Approved to Perform Follow-Up Services.

(a) An Applicant laboratory seeking approval from the Department to perform prenatal cytogenomic and/or cytogenetic tests on amniotic fluid and/or chorionic villus samples from State-approved Comprehensive or Satellite Prenatal Diagnosis Centers for California Prenatal Screening Program referrals, shall submit an application to the Department by mail. Each application shall contain the following information:

(1) A Laboratory Director Statement shall:

(A) Affirm the Director of the Applicant laboratory is a physician or holds a doctorate degree, has training and experience as a Clinical Cytogeneticist directing a cytogenetics

laboratory, and is certified by the American Board of Medical Genetics and Genomics or Canadian College of Medical Genetics in Clinical Cytogenetics.

(B) State the name, address, telephone, and facsimile number of the Applicant laboratory.

(C) Include the Clinical Laboratory Improvement Amendments (CLIA) certificate number and the California Laboratory License number of the Applicant laboratory.

(D) Include the Laboratory Director's signature, full name, and date of signing.

(E) Include the California License Number of the Laboratory Director, licensed in California as a Clinical Cytogeneticist.

(F) Affirm the Applicant laboratory has the capacity to meet the annual test volume requirements in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

(G) Affirm the Applicant laboratory has participated in, and successfully completed, the State of California-provided or approved laboratory inspection proficiency testing and/quality control program.

(H) Affirm the Applicant laboratory has resources for the determination of alpha fetoprotein and acetylcholinesterase concentrations in amniotic fluid for diagnosis of neural tube defects. If resources are to be provided by another facility, an Alpha Fetoprotein/Acetylcholinesterase Concentration Determination Statement must be attached and include the following information:

1. Name of the Applicant laboratory.
2. Affirm Applicant laboratory has access to resources for the determination of alpha fetoprotein and acetylcholinesterase concentrations in amniotic fluid for diagnosis of neural tube defects.
3. Name of the laboratory providing these resources.
4. CLIA certificate number of the laboratory providing these resources.
5. California Laboratory License number of the laboratory providing these resources.
6. Address, telephone, and facsimile number of the laboratory providing these resources.

7. Name, signature, and date of signing by the Laboratory Director of the laboratory providing these resources.

8. California License number of the Laboratory Director of the laboratory providing these resources.

(l) For chorionic villus sampling laboratory Applicants, affirm the Applicant laboratory has the capacity for cultures to include tissue culture of villus core.

(2) Evidence of quality assurance and quality control policies enacted for the implementation of each prenatal cytogenetic test (karyotyping of amniotic fluid or chorionic villi cells) the Applicant laboratory is applying to be authorized to perform on prenatal specimens from California Prenatal Screening Program referrals. Applicant Laboratories must establish a consultative affiliation with a laboratory that is approved by the Department to perform the relevant cytogenetic test on prenatal specimens from California Prenatal Screening Program referrals, and is financially independent of the Applicant laboratory, to split and proficiently analyze consecutive samples for clinical diagnosis, as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference. Evidence of quality assurance and quality control policies must include:

(A) An affirmation that the Applicant laboratory has performed the tests in accordance with the requirements of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference, has enacted quality assurance/quality control policies for the ongoing monitoring of prenatal testing, and acknowledges the documentation submitted is open to public inspection.

(B) The name of the Applicant laboratory.

(C) The Applicant laboratory's CLIA certificate number.

(D) The Applicant laboratory's California Laboratory License number.

(E) The name, signature, and date of signing by the Director of the Applicant laboratory.

(F) The name of the laboratory approved by the Department to perform cytogenetic tests on prenatal specimens from California Prenatal Screening Program referrals and with which the Applicant laboratory established a consultative affiliation.

(G) The CLIA certificate number of the laboratory with which the Applicant laboratory established a consultative affiliation.

- (H) The California Laboratory License number of the laboratory with which the Applicant laboratory established a consultative affiliation.
 - (I) The name of the Laboratory Director of the laboratory with which the Applicant laboratory established a consultative affiliation.
 - (J) The signature of the Laboratory Director of the laboratory with which the Applicant laboratory established a consultative affiliation.
 - (K) The date signed by the Laboratory Director of the laboratory with which the Applicant laboratory established a consultative affiliation.
 - (L) A comparison of the test results of samples analyzed by both the Applicant and the consultative affiliate laboratories, itemizing the cases.
- (3) Evidence that the Applicant laboratory has access to cytogenomic testing (prenatal microarray testing) with the enactment of appropriate quality assurance and quality control policies. The evidence must include:
- (A) For Applicant laboratories applying to be authorized to perform prenatal microarray testing and analysis, an application that includes:
 - 1. An affirmation of the accuracy and completeness of the information provided in the application and the validation study, and an acknowledgement that the documentation submitted is a public document open to public inspection.
 - 2. The name of the Applicant laboratory.
 - 3. The address of the Applicant laboratory.
 - 4. The Applicant laboratory's CLIA certificate number.
 - 5. The Applicant laboratory's California Laboratory License number.
 - 6. The name, signature, and date of signing by the Clinical Cytogenetics Laboratory Director/Technical Supervisor of the Applicant laboratory.
 - 7. The Clinical Cytogenetics Laboratory Director's/Technical Supervisor's California License Number.
 - 8. A description of the platform, including vendor, type of array, and the number of probes.
 - 9. The criteria for designating copy number changes, including minimum number of affected probes and/or minimum aberration size.

10. The specimen type(s) to be tested (cultured/uncultured).
 11. The criteria to accept and reject individual specimens.
 12. Quality assurance (QA) parameters monitored to ensure reliability of data.
 13. Details of the types of information reported (with reportable levels, such as size cut-offs) for copy number changes; absence of heterozygosity (loss of heterozygosity, regions of homozygosity, and long contiguous stretches of homozygosity); and mosaicism.
 14. A summary of the criteria to classify aberrations as clinically relevant, benign, or of unknown clinical relevance.
 15. Details on target turnaround times (TAT) and actual TAT on prenatal samples.
 16. A statement as to when abnormal results are confirmed and by what method (a statement of Standard Operating Procedure).
 17. A statement as to when testing for maternal cell or sibling contamination is performed and by what method (a statement of Standard Operating Procedure).
 18. A narrative statement describing validation studies that includes specimen types and clinical features for validation specimens.
 19. Validation and precision studies that demonstrate the proficient analysis of previously characterized samples by microarray, as outlined in the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
 20. A copy of relevant contents from the laboratory's Standard Operating Procedure specifying criteria to classify aberrations as clinically relevant, benign, or of unknown clinical relevance.
 21. Sample reports for abnormal finding/s, and variant/s of unknown significance.
 22. Evidence of participation in an external proficiency testing program for microarray (CAP Surveys); or
- (B) For Applicant laboratories applying to perform only cytogenetic tests, a Prenatal Microarray Statement that includes:
1. The name of the Applicant laboratory.

2. Affirmation the Applicant laboratory has access to prenatal microarray testing.
3. The name of the laboratory approved by the Department to perform cytogenomic tests on prenatal specimens from California Prenatal Screening Program referrals and will provide this testing.
4. The CLIA certificate number of the laboratory providing this testing.
5. The California Laboratory License number of the laboratory providing this testing.
6. The address, telephone and facsimile numbers of the laboratory providing this testing.
7. The name, signature, and date of signing by the Laboratory Director of the laboratory providing this testing.
8. The California License number of the Laboratory Director of the laboratory providing this testing.

(4) A copy of the Applicant laboratory's CLIA certificate.

(5) A copy of the Applicant laboratory's California Laboratory License.

(6) If an Applicant laboratory holds a license or permit as a clinical laboratory, with approval to perform prenatal cytogenomic and/or cytogenetic test/s, issued by a state in which the clinical laboratory standards, including standards for validation studies for prenatal cytogenomic and/or cytogenetic test approval, are equal to or exceed the Department's standards, as determined by the Department, the Applicant laboratory may submit these validation studies to the Department as evidence of meeting the validation requirements of this section.

(b) A laboratory that is approved by the Department to perform a prenatal cytogenetic test on amniotic fluid and/or chorionic villus samples from State-approved Comprehensive or Satellite Prenatal Diagnosis Centers for California Prenatal Screening Program referrals, and is seeking approval to perform an additional prenatal cytogenetic or cytogenomic test(s), shall submit an application to the Department that contains the information required in subsection (a) pertaining to the test(s).

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6547. Requirements for Laboratories for Continued Approval to Perform Follow-Up Services.

Continued approval to perform cytogenomic and/or cytogenetic tests on amniotic fluid cell culture and analysis and/or chorionic villus samples from State-approved Comprehensive or Satellite Prenatal Diagnosis Centers for California Prenatal Screening Program referrals is dependent on compliance with the provisions of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.

Section 6548. Suspension and Revocation of Laboratory Approval to Perform Follow-Up Services.

Approval for laboratories to perform cytogenomic and/or cytogenetic tests on amniotic fluid and/or chorionic villus samples from State-approved Comprehensive or Satellite Prenatal Diagnosis Centers for California Prenatal Screening Program referrals may be suspended or revoked by the Department if the laboratory:

- (a) Knowingly makes a false statement of fact or omits to state a fact on an application that would have resulted in the denial of approval.
- (b) Fails to comply with the provisions of the Prenatal Diagnosis Center Standards and Definitions ~~2018~~2022, incorporated by reference.
- (c) Fails to operate and furnish services in compliance with all other applicable state laws, regulations, and local ordinances.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125065 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 124990, 125000, 125001, 125050, 125055 and 125065, Health and Safety Code.