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 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 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 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 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 participants ~~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 certification exam; and

(B) Performance of 25 second trimester procedures on 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 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.

(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~~ fetal autosomal trisomies, sex chromosome aneuploidies, and other genetic conditions detectable by cfDNA screening.

(10) “California Prenatal Screening Program” means the Department's legislatively-mandated, state-wide program that includes cell-free DNA screening and maternal plasma and serum alpha-fetoprotein test(s) for prenatal screening for birth defects and authorized follow-up services for individuals with a screen positive test.

(11) “Cell-free DNA screening” means a prenatal screening test for fetal autosomal trisomies, sex chromosome aneuploidies, fetal sex, and other genetic conditions detectable by cfDNA screening performed on maternal plasma after 10 weeks 0 days of gestation.

(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 participants ~~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 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~~

participants 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 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~~ participants 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 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~~ participants.

(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~~ participants.

(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 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 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 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 individuals planning to continue their pregnancies.

(24) “Fetal autosomal trisomies” means trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome).

(25) “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.

(26) “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~~ participants at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers.

(27) “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 individual.

(28) “Inadequate specimen for cell-free DNA screening” means a blood specimen collected from a pregnant individual which is not suitable in quality or quantity, a blood specimen was collected before 70 days (10 weeks 0 days), or clinical information was not documented as required for test result interpretation to perform valid prenatal screening for fetal autosomal trisomies.

(29) “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 was collected before 15 weeks 0 days (105 days) or after 21 weeks 0 days (147 days) of gestation, or clinical information not documented for test result interpretation to perform valid prenatal screening for neural tube defects of the fetus.

(30) “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~~ participants 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 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 2022, incorporated by reference.

(31) "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 participants ~~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 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 2022, incorporated by reference.

(32) "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 participants ~~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 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 2022, incorporated by reference.

(33) "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 2022, incorporated by reference.

(34) “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 participants ~~patients~~ services provided for California Prenatal Screening Program referrals at the State-approved Comprehensive Prenatal Diagnosis Center and any State-approved Satellite Prenatal Diagnosis Centers.

(35) “Maternal Serum Alpha Fetoprotein screening” means a prenatal screening test on maternal serum for the determination of risk for fetal neural tube defects between 15 weeks 0 days and 21 weeks 0 days of gestation.

(36) “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.

(37) “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.

(38) “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.

(39) “Prenatal birth defects screening laboratory” means a laboratory or laboratories approved by the Department to conduct prenatal screening for fetal autosomal trisomies, sex chromosome aneuploidies, fetal sex, and other genetic conditions detectable by cfDNA screening as determined by the Department, or prenatal screening for neural tube defects as part of state administered testing.

(40) “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.

(41) “Prenatal screening for fetal autosomal trisomies” means a cell-free DNA 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 after 10 weeks 0 days of gestation.

(42) "Prenatal screening for neural tube defects" means a maternal serum screening test provided by Department-approved prenatal birth defects screening laboratories. Serum screening consists of a test for maternal serum alpha-fetoprotein in the second trimester of pregnancy.

(43) "Prenatal screening for sex chromosome aneuploidies" means a cell-free DNA screening test provided by a Department-approved prenatal birth defects screening laboratory (or laboratories) for atypical number of X and/or Y-chromosomes beyond the typical female (XX) or male (XY) complement after 10 weeks 0 days of gestation.

~~(43)~~(44) "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 participants ~~patients~~ not referred ~~by~~ through 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.

~~(44)~~(45) "Screening Information System" means the computerized system used by the Department and external stakeholders for the management of screening data and patient service records.

~~(45)~~(46) "Screen positive test result" means a cell-free DNA screening test result or maternal serum alpha-fetoprotein 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.

(47) "Sex chromosome aneuploidy" means an atypical number of X and/or Y-chromosomes beyond the typical female (XX) or male (XY) complement.

~~(46)~~(48) “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.

~~(47)~~(49) “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.

~~(48)~~(50) “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 participants ~~patients~~ at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Board Certification by 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 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 2022, incorporated by reference.

~~(49)~~(51) "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 participants ~~patients~~ at State-approved Comprehensive or Satellite Prenatal Diagnosis Centers, and meets the following requirements for initial approval:

(A) Board Certification by 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 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 2022, incorporated by reference.

~~(50)~~(52) “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~~ Only prenatal birth defects screening laboratories~~. Such laboratories shall be licensed~~ certified as clinical laboratories in compliance with the federal and state regulations under Division 2, Chapter 3 (commencing with Section 1200) of the Business and Professions Code in contract with the Department may participate in the California Prenatal Screening Program.

(b) ~~Approved p~~ Prenatal birth defects screening laboratories that choose to participate in the California Prenatal Screening Program 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 prenatal screening for fetal autosomal trisomies, sex chromosome aneuploidies, fetal sex if requested, and other genetic conditions detectable by cfDNA screening as determined by the Department, or prenatal screening for neural tube defects to pregnant individuals, in a quantity specified in their contract, plus an emergency testing capacity that will be specified by contract.

(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~~ Clinical laboratories ~~approved by the Department~~ participating in the California Prenatal Screening Program shall comply with all laboratory standards for quality

assurance ~~issued by the Department~~ in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) specified in section 1202.5 of the Business and Professions Code 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 maternal serum alpha fetoprotein concentration shall be designated and/or approved by the Department. Analytical methods to be used in the prenatal screening for fetal autosomal trisomies shall be approved by the Department.~~

~~(e) Only Department approved prenatal birth defects screening laboratories shall offer or provide prenatal screening for fetal autosomal trisomies or prenatal screening for neural tube defects that are included in the Department's Prenatal Screening Program to California residents.~~

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 6527. Clinician Requirements.

(a) Clinicians shall provide or cause to be provided to all pregnant individuals in their care before 21 weeks 0 days (147 days) of gestation, or before 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 individual.

(b) The provisions of subsection (a) shall not apply if the pregnant individual has completed more than 21 weeks 0 days (147 days) of gestation or 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 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 fetal autosomal trisomies, sex chromosome aneuploidies, and other genetic conditions as determined by the Department, 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~~ complete ~~a~~ consent documentation in a format provided by the Department, the circumstances of which are to be documented in the medical record. Maternal plasma and serum specimens must be accompanied by the pregnant individual's ~~signed and~~ completed Department-designated consent form to be analyzed for screening.

(d) Clinicians must offer patients the opportunity to accept or reject screening for fetal sex detection and must record the patient's choice on the test requisition form.

(e~~d~~) If the pregnant 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~~f) Blood collection forms and 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 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~~g) 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~~h) For each 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 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 60 calendar days of the end of the pregnancy, the outcome of pregnancy and status of each fetus, or infant resulting therefrom.

(~~h~~i) The test results shall be confidential so that such information shall only be released with the knowledge and specific written consent of the 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~~j) 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 individual.

(~~j~~k) 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.

Article 4. California Prenatal Screening Program Fee Collection

Section 6540. Program Participation Fees.

(a) The all-inclusive program participation fee for prenatal screening for neural tube defects, shall be $85.00. The fee shall be paid to the Department by the individual being tested or by any third party which is legally responsible for 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 fetal autosomal trisomies shall be $344.00~~$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) Any third party responsible for the prenatal healthcare of any individual that opts to participate in the California Prenatal Screening Program, 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., shall not:

(1) Require prior authorization for California Prenatal Screening Program cfDNA or MSAFP screening test fees before covering the cost for services; or

(2) Delay or defer payment of services pending the receipt of medical records or report.

~~(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.

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)–(E) *No changes to text.*

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

(G)-(J) *No changes to text.*

(2)-(3) *No changes to text.*

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

(A) –(I) *No changes to text.*

(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.-5. *No changes to text.*

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 participant ~~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.-8. *No changes to text.*

(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) – (I) *No changes to text.*

(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.-5. *No changes to text.*

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 participant ~~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.-8. *No changes to text.*

(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)-(I) *No changes to text.*

(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.-5. *No changes to text.*

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 participant ~~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)-(12) *No changes to text.*

(b) –(k) *No changes to text.*

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.