

California Department of Public Health
Genetic Disease Screening Program

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**PRENATAL DIAGNOSIS CENTER
STANDARDS AND DEFINITIONS
2011**

I. Comprehensive Prenatal Diagnosis Center

A Comprehensive Prenatal Diagnosis Center is an established center with a complete range of prenatal diagnosis services and full-time multidisciplinary medical staff as follows:

- A. Has a Director who is certified in Clinical Genetics by the American Board of Medical Genetics. The Director is responsible for such administrative duties as:
1. The supervision and the quality of testing, counseling, and medical care provided by all clinical members of the Prenatal Diagnosis Center staff, including Satellites;
 2. Assurance that participation in prenatal diagnosis procedures by any pregnant woman is voluntary;
 3. Notifying the GDSP within ten working days of:
 - a. Any changes in locations where services are provided or in staffing of locations, including a plan to meet the Standards on an interim and permanent basis; and
 - b. Any case of maternal mortality that could possibly be related to or associated with prenatal diagnosis;
 4. The acceptance for prenatal diagnosis of all pregnant women referred from state funded or administered programs; and
 5. The timely submission of required reports including reports on each patient with abnormal results, quarterly prenatal diagnosis center reports, and all practitioners' Adverse Outcome Studies.
 6. The acceptance of site visits by state staff or designated state agents and to make available confidential patient reporting systems, billing and medical records needed to monitor compliance with the PDC Standards and California Prenatal Screening Program Guidelines.

- B. The Director or other Clinical Geneticist(s) certified in Clinical Genetics by the American Board of Medical Genetics must:
1. Be available to provide consultation in person within three working days to all families with abnormal or questionable results. The consultation offer must be documented in the patient's chart; and
 2. Supervise all professional services and be responsible for the evaluation of work performance by reviewing and signing off on all patient charts. The Clinical Geneticist must sign the chart within 30 days of the final date of service. The signature indicates a review of the family history, ultrasound findings, amniocentesis or CVS consent form or documentation of decline to ensure appropriate services meeting State Standards have been provided. The chart must also be reviewed for the amniocentesis or CVS results and documentation that the results and all significant clinical information have been sent to the referring physician. If the amniocentesis or CVS results are normal, this last review may be performed by a Board certified Genetic Counselor. If the results are abnormal, this review must be performed by a Clinical Geneticist and there must also be documentation of appropriate consultation offered to the patient. A Clinical Geneticist may be responsible for supervision of services to no more than 200 prenatal patients per week.

In Sections C, K, and L, the number of procedures excludes repeat insertions.

- C. Has ultrasound-guided amniocentesis available at greater than/equal to 15 weeks gestation (standard amniocentesis). This is performed by physicians who:
1. Have previously completed 100 second trimester procedures under the supervision of a physician experienced in ultrasound guided amniocentesis. Each of the physicians performing or supervising the procedures must have specific knowledge and experience with:
 - a. The collection by second trimester amniocentesis of 50 amniotic fluid samples per year for cell culture and analysis. Once the practitioner has successfully completed two Adverse Outcome Studies for amniocentesis, the practitioner must collect at least 25 amniotic fluid samples annually;
 - b. Obstetrical ultrasonography; and
 - c. Basic genetic information and appropriate counseling procedures for chromosomal, biochemical and neural tube defects.
 2. Provisional approval to perform amniocentesis may be given to Interim Approval Amniocentesis Practitioners. Each Interim Approval Amniocentesis Practitioner must:
 - a. Currently be in a Maternal-Fetal Medicine or equivalent specialized training program or have completed a Maternal-

Fetal Medicine or equivalent specialized training program;
and

- b. Have completed a minimum of 50 second trimester amniocentesis procedures on women planning to continue their pregnancies, performed under the direct supervision of an experienced amniocentesis practitioner with the supervising practitioner in the room; and
 - c. Complete the remaining 50 second trimester amniocentesis procedures under supervision within a defined time period; with the supervising practitioner onsite, within immediate access to the patient; and
 - d. Submit a log of the second 50 supervised procedures to the Genetic Disease Screening Program for review. The practitioner will be granted full approval as an Amniocentesis practitioner and then they must begin collecting Adverse Outcome data on consecutive amniocentesis procedures.
3. If the amniocentesis is performed by a physician other than an Obstetrician/Gynecologist (OB/GYN), an OB/GYN with American Board of Obstetrics and Gynecology certification/Active Candidate status or equivalent must be available on an emergency on-call basis in case of amniocentesis complications. The Genetic Disease Screening Program is to be notified whenever such an OB/GYN specialist is called on an emergency basis.
- D. Has consultative ultrasonography available which is performed by a physician on site who:
1. Is Board certified in Radiology or OB/GYN or the equivalent. (If they are not Board certified, they must be an active candidate for the next Board examination.); and
 2. Has completed a fellowship and had supplemental subspecialty training in:
 - a. maternal/fetal medicine or clinical genetics; or
 - b. diagnostic radiology, body imaging or the equivalent with an emphasis upon fetal medicine.

The supplemental training must be at a facility that performs at least 2000 second trimester fetal ultrasound exams a year and that meet the anatomical guidelines of the AIUM/ACR for complete fetal examinations. The supplemental training must include at least three months of targeted fetal ultrasound examinations that involve high-risk obstetric imaging and must include basic physics, techniques, performance, and interpretation followed by three months of proctoring, i.e., co-reading, by a qualified consultative sonologist; and

3. Has previously performed 500 detailed second trimester ultrasound exams on patients referred specifically for the detection of fetal abnormalities. Indications would 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.

The emphasis of these examinations is a detailed and targeted survey of fetal anatomy for malformations and must include:

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; and

4. The solo practice consultative sonologist must perform a minimum of 200 detailed second trimester prenatal ultrasound exams annually on pregnancies at risk for fetal abnormalities. Each group practice consultative sonologist shall perform at least 150 detailed second trimester prenatal ultrasound exams annually on pregnancies at risk for fetal abnormalities. A group practice is defined as a situation where all consultative sonologists practice at the same location.
5. All ultrasound practices at State-approved Prenatal Diagnosis Centers must be accredited by the American College of Radiology (ACR) or the American Institute of Ultrasound in Medicine (AIUM).
6. All State-approved Prenatal Diagnosis Centers authorized to provide fetal echocardiography must be accredited by the American Institute of Ultrasound in Medicine (AIUM).
7. Must be able to perform first trimester ultrasound exams on patients referred specifically due to identification of a Large Nuchal Translucency as defined by the Genetic Disease Screening Program.

The emphasis of these examinations is a detailed and targeted survey of fetal anatomy for malformations and must include:

fetal number, documentation of fetal life, placental localization, amniotic fluid volume, gestational dating, detection and evaluation of maternal pelvic mass, and a survey of fetal anatomy appropriate for the gestational age of the patient.

Any exceptions to the above criteria may be presented to an ultrasonographers' review panel for their recommendations regarding equivalent background and experience. Final decisions are made by the Genetic Disease Screening Program.

- E. Provides all clients choosing to terminate the pregnancy referral to a facility with assured access to second trimester abortions by a method

which usually allows confirmation of diagnosis unless medically contraindicated.

F. Has genetic counseling services which are performed by a qualified Genetic Counselor, Clinical Geneticist, or Ph.D. Medical Geneticist. At least one Genetic Counselor at each approved center must be Board certified or have Active Candidate status and pass the next Board examination.

1. A qualified Genetic Counselor is defined as:

a. A person who has been certified by the American Board of Medical Genetics (ABMG) or American Board of Genetic Counseling (ABGC); or

b. A graduate from a Master's or Ph.D. program in genetic counseling from an ABGC or equivalent accredited training program who has Active Candidate Status as defined by the ABGC for the 2011 ABGC certification examination, if the individual graduated in 2010 or earlier. Graduates in 2011 are required to have Active Candidate Status for the 2012 certification examination if they do not apply to sit for the 2011 certification examination; or

c. A person who is considered eligible to apply for Active Candidate status or has Active Candidate Status as defined by the American Board of Genetic Counseling (ABGC) and who has taken the ABGC certification examination either for the first or second time and failed the latest ABGC certification exam taken. However, a Board certified Genetic Counselor, Ph.D. Medical Geneticist or Clinical Geneticist at the center must review and sign off on all cases on a weekly basis until Board certification is achieved.

An individual who is no longer considered eligible for Active Candidate Status or does not have Active Candidate Status due to failing the ABGC certification exam for a third time or more will be designated as a Genetic Assistant until July 1, 2011. After July 1, 2011 these individuals will not be authorized to provide genetic counseling until a genetic counselor license is obtained.

An individual who is not given Active Candidate status until the administration of the examination, but is able to sit for the ABGC certification examination by approval of the ABGC, will be designated as a Genetic Assistant until July 1, 2011. After July 1, 2011 these individuals will not be authorized to provide genetic counseling until a genetic counselor license is obtained.

d. By December 31, 2011, all genetic counselors and Ph.D. Medical Geneticists must be licensed or have been issued a

temporary genetic counselor license by the California Department of Public Health.

2. Genetic Assistant is defined as an R.N. licensed by the Board of Registered Nursing with a minimum of a bachelor's degree in nursing and/or a person who has an earned bachelors, masters, or doctoral degree in nursing, biological sciences or other appropriate field. Genetic Assistants may only counsel patients who do not have a high risk of unusual or other potentially complex genetic abnormalities that are suspected as the result of previous family history, clinical investigation or laboratory tests. All Genetic Assistants must be directly supervised by a Board certified Genetic Counselor, Clinical Geneticist, or Ph.D. Medical Geneticist. Direct supervision is defined as the review of all cases on a weekly basis and documentation of such by signature.

As of July 1, 2011, Genetic Assistants will no longer be approved to provide genetic counseling services.

3. Prior to CVS and/or amniocentesis procedures, each woman must be offered genetic counseling under the supervision of a Clinical Geneticist and provide informed consent.
4. Genetic Counselors, Ph.D. Medical Geneticists, and Genetic Assistants must attend continuing education courses, conferences, and/or grand rounds on genetically related topics for 30 hours within a two year period.
5. All patients seen for genetic counseling must have a genetic risk assessment that includes the minimal elements contained in the Prenatal Genetic Screening Questionnaire and/or Pedigree. A pedigree is required if the patient, partner or fetus is at increased risk for a genetic disorder due to a significant family history indicated on the questionnaire.

G. Utilizes a Genetic Disease Screening Program approved cytogenetics laboratory as evidenced by:

1. Direction by a cytogeneticist (M.D. and/or Ph.D.) certified as such by the American Board of Medical Genetics, and licensed by the State of California to direct a clinical cytogenetics laboratory.
2. Testing performed by boarded or certified testing personnel, licensed by the State of California to perform clinical cytogenetic testing.
3. Compliance with the Pacific Southwest Regional Genetics Network (PSRGN) cytogenetic testing guidelines.
4. Prior to independent prenatal cell culture and analysis, a new applicant center must meet criteria 1-3 above and provide evidence of quality assurance and quality control policies for the implementation of prenatal testing. This must include establishing

a consultative affiliation with an approved laboratory which is financially independent of the applicant agency for the first 25 samples of any new prenatal test, a review of the first 25 results of any test, and ongoing quality assurance/quality control indicators once the test is validated. Review of the first 25 samples by both applicant and consultative affiliate laboratories must be documented in a letter itemizing the cases and include a general overview of the quality assurance/quality control policies enacted for the ongoing monitoring of prenatal testing. A record of this review must be kept for ten years in an easily retrievable form.

5. Ability to perform or arrange for dysmorphism evaluation and/or pathologic examination of abortuses as well as cytogenetic and biochemical procedures.
 6. Continuing analyses of not less than 200 prenatal cell cultures per year with final results to meet turnaround times as outlined in the approved cytogenetic testing guidelines.
 7. Participation in and successful completion of any State of California provided or approved laboratory inspection, proficiency testing and/or quality control program including submission of appropriate documentation of participation and results.
 8. Submission of a written list identifying other recognized laboratories which have been used for the performance of specialized investigations for inherited diseases including biochemical and DNA studies.
 9. Assured access to resources for the determination of alpha fetoprotein and acetylcholinesterase concentrations in amniotic fluid for diagnosis of neural tube defects.
- H. Any trainee performing genetic services in a Prenatal Diagnosis Center must be under the direct, constant and on-site supervision of an appropriate specialist on the staff of an approved Comprehensive Prenatal Diagnosis Center.
- I. An interdisciplinary meeting of the Comprehensive Prenatal Diagnosis Center staff including ultrasonography, amniocentesis practitioner, genetic counseling, and medical genetics staff must be held at least once every three months.
- J. If a staff change(s) occurs such that an approved center no longer has the services of a Clinical Geneticist, a Medical Geneticist, Cytogeneticist, and/or Genetic Counselor certified by their respective Boards, whenever certification is required by these Standards, the personnel hired must be certified or have Active Candidate status and pass the next sitting of their Board certification exams. Until the time of Board certification, the center Director will arrange for consultation and supervision of the appropriate areas by outside personnel who are Board certified and notify the Genetic Disease Screening Program of the consultation arrangement. All other

changes in Prenatal Diagnosis Center staff referred to in these Standards must meet the criteria as described in Sections C, D, K, and L (if applicable).

- K. Where all transcervical Chorionic Villus Sampling (TC CVS) procedures are performed by:
1. Physicians who are American Board of Obstetrics and Gynecology certified/Active Candidates or equivalent, and have had specific training and special expertise in prenatal diagnosis. This training must include detailed obstetrical ultrasonography, as well as basic genetic information and appropriate counseling procedures for chromosomal, biochemical, and neural tube defects. Such physicians shall have:
 - a. Performed a total of at least 25 TC CVS procedures. These may be performed on women who are not planning to continue their pregnancies or on women referred for prenatal genetic indications and planning to continue their pregnancies. However, a minimum of 5 TC CVS procedures must be performed on women 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 OB/GYN who is experienced in TC CVS. (Experienced is defined as having performed at least 25 TC CVS procedures on women continuing their pregnancies.); and
 - b. Been approved as TA CVS practitioners or meet the Standards for approval as a TA CVS practitioner.
 2. Provisional approval to perform Transcervical Chorionic Villus Sampling procedures may be given to Interim Approval TC CVS Practitioners. Each Interim Approval TC CVS Practitioner must
 - a. Currently be in a Maternal-Fetal Medicine or equivalent specialized training program or have completed a Maternal-Fetal Medicine or equivalent specialized training program; and
 - b. Have completed a minimum of 12 first trimester TC CVS procedures on women planning to continue their pregnancies, performed under the direct supervision of an experienced TC CVS practitioner with the supervising practitioner in the room; and
 - c. Complete the remaining 13 TC CVS procedures under supervision within one year, with the supervising practitioner onsite, within immediate access to the patient; and
 - d. Submit a log of the 13 or remaining supervised TC CVS procedures to the Genetic Disease Screening Program for review. The practitioner will be granted full approval as a TC

CVS practitioner and then they must begin collecting Adverse Outcome data on consecutive TC CVS procedures.

3. Each of the physicians performing or supervising TC CVS must perform at the rate of at least 25 CVS procedures, with at least 5 being TC CVS procedures, annually on women planning to continue their pregnancies.

L. Where all transabdominal Chorionic Villus Sampling (TA CVS) procedures are performed by:

1. Physicians who are American Board of Obstetrics and Gynecology certified/Active Candidates or equivalent; and have had specific training and special expertise in prenatal diagnosis. This training must include detailed obstetrical ultrasonography, as well as basic genetic information and appropriate counseling procedures for chromosomal, biochemical, and neural tube defects. Such physicians shall have:

- a. Been approved for and experienced in the performance of amniocentesis with ultrasound guidance, and have performed at least 25 TA CVS procedures. These may be performed on women who are not planning to continue their pregnancies or on women referred for prenatal genetic indications and planning to continue their pregnancies. However, a minimum of 5 TA CVS procedures must be performed on women 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 OB/GYN who is experienced in TA CVS. (Experienced is defined as having performed a minimum of 25 TA CVS procedures on women planning to continue their pregnancies); or
- b. Performed a minimum of 10 Percutaneous Umbilical Blood Sampling (PUBS) procedures or fetal intravenous transfusions on women planning to continue their pregnancies followed by a minimum of 15 TA CVS procedures with on-site supervision in the procedure room of a physician experienced in TA CVS; or
- c. Been approved as a TC CVS practitioner and an amniocentesis practitioner; or
- d. Met the Standards for approval as a TC CVS practitioner and amniocentesis practitioner.

3. Provisional approval to perform Transabdominal Chorionic Villus Sampling procedures may be given to Interim Approval TA CVS Practitioners. Each Interim Approval TA CVS Practitioner must

- a. Currently be in a Maternal-Fetal Medicine or equivalent specialized training program or have completed a Maternal-

- Fetal Medicine or equivalent specialized training program;
and
- b. Have completed a minimum of 12 first trimester TA CVS procedures on women planning to continue their pregnancies, performed under the direct supervision of an experienced TA CVS practitioner with the supervising practitioner in the room; and
 - c. Complete the remaining 13 TA CVS procedures under supervision within one year, with the supervising practitioner onsite, within immediate access to the patient; and
 - d. Submit a log of the 13 or remaining supervised TA CVS procedures to the Genetic Disease Screening Program for review. The practitioner will be granted full approval as a TA CVS practitioner and then they must begin collecting Adverse Outcome data on consecutive TA CVS procedures.
4. Each of the physicians performing or supervising TA CVS must perform at the rate of at least 25 CVS procedures (TC CVS, TA CVS or combination of both) annually on women planning to continue their pregnancies.
- M. In Centers offering CVS, if either TA or TC CVS is clinically contraindicated or unsuccessful, an appropriate alternative prenatal diagnosis procedure must be available either at that Prenatal Diagnosis Center or a referral must be made to another State-approved Prenatal Diagnosis Center.
- N. All amniocentesis and CVS practitioners must accumulate pregnancy outcome data as indicated on the adverse outcome form. Practitioners performing prenatal diagnostic procedures must report on a statistically significant number of women who have had prenatal diagnostic amniocentesis or CVS procedures and who are planning to continue their pregnancies. Amniocentesis practitioners are required to report the outcome of each procedure performed between 14 weeks 0 days and 14 weeks 6 days gestation. Centers must submit each prenatal diagnostic practitioner's individual adverse outcome rate.
1. Studies with a start date prior to January 1, 2007: The adverse outcome rate is defined as the fetal loss rate minus the anomaly loss rate. The fetal loss rate is defined as the number of fetuses expiring at any time after the prenatal diagnostic procedure up to/equal to 28 weeks gestation divided by the total number of viable fetuses at the time of the prenatal diagnosis procedures. The anomaly loss rate is defined as the number of fetuses with congenital anomalies, genetic disorders, or chromosome abnormalities expiring at any time after the prenatal diagnosis procedure up to/equal to 28 weeks gestation divided by the total number of viable fetuses at the time of the prenatal diagnosis procedure.

2. Studies with a start date of January 1, 2007, will have the fetal loss rate defined as the number of fetuses expiring at any time after the prenatal diagnostic procedure up to/equal to 24 weeks gestation divided by the total number of viable fetuses at the time of the prenatal diagnosis procedures. Studies with a start date of January 1, 2007, will have the anomaly loss rate defined as the number of fetuses with congenital anomalies, genetic disorders, or chromosome abnormalities expiring at any time after the prenatal diagnosis procedure up to/equal to 24 weeks gestation divided by the total number of viable fetuses at the time of the prenatal diagnosis procedure. The adverse outcome rate is statistically adjusted to account for patients who are lost to follow-up).

If the adjusted adverse outcome rate of an amniocentesis practitioner is greater than 3 percent, an early amniocentesis practitioner is greater than 5 percent, or CVS practitioner is greater than 6 percent, the Genetic Disease Screening Program with the assistance and advice of an appointed committee of Prenatal Diagnosis Center experts will evaluate and make a determination regarding the appropriateness of that physician to continue as an approved prenatal diagnosis practitioner.

3. For practitioners with a start date of January 1, 2010 or greater: The Prenatal Diagnosis Center will be required to report on outcomes obtained at the time of reporting cytogenetic results, every six months, until a statistically significant number of outcomes are obtained and their study is considered complete.
- O. Each Prenatal Diagnosis Center must maintain a minimum annual volume of 100 women seen for prenatal genetic services. Prenatal genetic services are defined as those genetic services relating to the outcome of pregnancies.
 - P. Each Prenatal Diagnosis Center must have an Internal Continuous Quality Improvement Program. The PDC Director must provide oversight to the program and work with PDC staff to achieve improvement goals.
 - Q. Whenever a Satellite Prenatal Diagnosis Center decides to switch affiliation to another Comprehensive Prenatal Diagnosis Center, the Satellite Center must submit a letter to the original Prenatal Diagnosis Center Director and to the Genetic Disease Screening Program informing them of their intent to switch affiliations. The original Prenatal Diagnosis Center Director must then submit a letter to the Genetic Disease Screening Program acknowledging the intent of the Satellite Center switch. The letter must include whether or not there are any outstanding issues with the site regarding compliance to the PDC Standards and California Prenatal Screening Program Guidelines. The letter must be sent to the Genetic Disease Screening Program within thirty days from the original request of the Satellite Center requesting the switch.

If there are outstanding data that are required to be submitted (e.g. quarterly Prenatal Diagnosis Center reports, Adverse Outcome Studies), the Genetic Disease Screening Program will not approve the switch until the data have been successfully completed and submitted to the Screening Program. It is the responsibility of the Satellite center requesting the switch to ensure that the data are complete before requesting the switch in affiliation. If the Comprehensive Prenatal Diagnosis Center that is taking on the new site(s) wants to assume the responsibility for completing the data, they must submit assurance in writing to the Genetic Disease Screening Program that the data will be submitted within a specified time period. The approval will be time limited until the data are submitted.

- R. Abnormal or ambiguous results of amniocentesis or CVS procedures must be verbally communicated to referring physicians and/or patients by clinical genetics staff such as M.D. Clinical Geneticists, Ph.D. Medical Geneticists, Clinical Cytogeneticists, or Genetic Counselors. The center must have a written protocol in place and must take responsibility for reporting normal results of amniocentesis or CVS procedures.
- S. Providers will be given provisional approval as TA CVS practitioners, TC CVS practitioners, or amniocentesis providers under the following terms:

- 1. Delinquent reporter

Approved amniocentesis and CVS practitioners who fail to provide adverse outcome data for more than two years from the study start date or submission of a progress report will be given provisional approval as a Delinquent Reporter. These Delinquent Reporters must report the outcomes of pregnancy via a progress report or log every six months until their studies are completed. If there is no submission of data or documentation of attempts to submit the data within six months of being given provisional status, practitioner approval will be withdrawn.

- 2. Category A Provisional Practitioner

Approved amniocentesis and CVS practitioners that have two consecutive years of low volume, defined as less than 50 second trimester amniocentesis procedures per year or less than 25 CVS procedures per year; and:

- a. Have not completed any adverse outcome studies; or
- b. Have completed one adverse outcome study; or
- c. Are Delinquent Reporters

will be given provisional approval as a Category A Provisional Practitioner.

These Category A Provisional Practitioners must complete a new adverse outcome study by reporting the outcomes of pregnancy via

a progress report or log every six months until their studies are completed. If there is no submission of data or documentation of attempts to submit the data within six months of being given provisional status, practitioner approval will be withdrawn.

3. Category B Provisional Practitioner

Approved amniocentesis and CVS practitioners that have successfully completed two adverse outcome studies, and then have two consecutive years of low volume, defined as less than 25 CVS or at least 25 second trimester amniocentesis procedures per year, will be given provisional approval as a Category B Provisional Practitioner.

These Category B Provisional Practitioners must:

- a. Complete a new adverse outcome study by reporting the outcomes of pregnancy via a progress report or log every six months until their studies are completed; and
- b. Be re-reviewed for approval status by the CQI Committee within one year of the Category B Provisional Practitioner status being awarded.

If there is no submission of data or documentation of attempts to submit the data within six months of being given provisional status, practitioner approval will be withdrawn.

4. A practitioner requesting a leave of absence for personal reasons or sabbatical leave should submit a letter to the Genetic Disease Screening Program (GDSP) outlining specific reasons for the request and listing any outstanding approval conditions or reporting compliance issues. Leave of absence requests will be reviewed by the Perinatal Subcommittee with final approval by GDSP.
5. In order to re-approve a TC CVS practitioner after one year of having practitioner approval status withdrawn, the practitioner must perform 5 TC CVS procedures with on-site supervision in the procedure room by an OB/GYN who is experienced in performing TC CVS. (Experienced is defined as having performed a minimum of 25 TC CVS procedures on women planning to continue their pregnancies.)
6. In order to re-approve a TC CVS practitioner after two years of having practitioner approval status withdrawn, the practitioner must perform 10 TC CVS procedures with on-site supervision in the procedure room by an OB/GYN who is experienced in performing TC CVS. (Experienced is defined as having performed a minimum of 25 TC CVS procedures on women planning to continue their pregnancies.)
7. In order to reapprove a TA CVS practitioner after having practitioner approval status withdrawn, the practitioner must be an

approved amniocentesis practitioner and must perform 5 TA CVS procedures with on-site supervision in the procedure room by an OB/GYN who is experienced in performing TA CVS. (Experienced is defined as having performed a minimum of 25 TA CVS procedures on women planning to continue their pregnancies.)

II. SATELLITE PRENATAL DIAGNOSIS CENTER

A Satellite Prenatal Diagnosis Center is a center with the following prenatal diagnosis services:

- A. Provides on site genetic counseling, ultrasonography, and the collection of amniotic fluid/CVS specimens at a site which is not in the same suite as an existing prenatal diagnosis center/satellite.
- B. Provides on-site counseling prior to CVS and/or amniocentesis by a Clinical Geneticist, Ph.D. Medical Geneticist, or Genetic Counselor who is Board certified or has Active Candidate Status. The Clinical Geneticist must be available whenever possible at the satellite site within three working days to provide consultation in person to all families with abnormal or questionable results. The Clinical Geneticist must be available within reasonable travel time (less than eight hours) to all assigned sites of service.
- C. The Clinical Geneticist will conduct monthly meetings with clinical staff who are assigned to the site to include, but not be limited to, case review.
- D. Has a written agreement with a State-approved Comprehensive Prenatal Diagnosis Center and an approved cytogenetic laboratory which also performs necessary laboratory studies. The Clinical Geneticist of the Comprehensive Prenatal Diagnosis Center will assume complete responsibility for the accuracy of genetic counseling. The Director of the Comprehensive Prenatal Diagnosis Center is responsible for the adequacy of the amniotic fluid/CVS samples and follow-up services.
- E. Has an established mechanism for safely and rapidly delivering satisfactory amniotic fluid/CVS samples to the affiliated Comprehensive Prenatal Diagnosis Center or to the approved cytogenetics laboratory.
- F. Complies with criteria B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, and S as described for a Comprehensive Prenatal Diagnosis Center.

Any requests for exceptions to the Standards must be documented in a letter to the Genetic Disease Screening Program requesting a waiver and outlining temporary coverage as well as future plans to comply with the Standards. Waivers will be considered only in extreme circumstances and must be justified as necessary to provide access to services in underserved areas. Final decisions are made by the Genetic Disease Screening Program.