

California Department of Public Health

Genetic Disease Screening Program

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PRENATAL DIAGNOSIS CENTER STANDARDS AND DEFINITIONS 2013

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 (PDC) staff, including Satellites;
 2. Assurance that participation in prenatal diagnosis procedures by any pregnant woman is voluntary;
 3. Notifying the Genetic Disease Screening Program (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. PDC sites are required to retain paper charts on-site for one year for chart audit. The retention of paper charts does not apply to institutions using electronic charting, as long as GDSP can access the necessary elements in the electronic chart.

7. Acceptance for continuity of care for the full complement of services offered under the Prenatal Screening Program. Whenever a fetal echocardiography examination is authorized, assurance that the procedure is available either at the Prenatal Diagnosis Center, at an accredited Fetal Echocardiography Laboratory or Ultrasound Practice that the Prenatal Diagnosis Center has a working relationship with or a referral must be made to another Fetal Echo approved site.
- 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. Obstetrical ultrasonography; and
 - b. 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 GDSP 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 GDSP is to be notified whenever such an OB/GYN specialist is called on an emergency basis.
- 4.
- a. The collection by second trimester amniocentesis of 25 amniotic fluid samples per year for cell culture and analysis. If a practitioner performs less than 25 amniocentesis procedures per year, the practitioner must accumulate pregnancy outcome data as indicated on the Adverse Outcome form until they reach the annual volume requirement, unless they are in an existing Adverse Outcome Study. Once the practitioner has successfully completed two Adverse Outcome Studies for amniocentesis, the practitioner must collect at least 15 amniotic fluid samples annually.
 - b. Any state-approved Amniocentesis Practitioner that provides direct supervision over a Fellow in an ABOG recognized Fellowship Program or another amniocentesis practitioner may include any supervised amniocentesis procedure(s) toward their annual volume requirement. Only the supervisor would count the procedure(s) towards their annual volume requirement. Supervised Fellows or other supervised amniocentesis practitioners are not authorized to perform amniocentesis procedures on patients referred

through the California Prenatal Screening Program, unless they have Full or Interim Approval as an Amniocentesis Practitioner.

- c. If an Amniocentesis Practitioner performs less than 5 amniocentesis procedures per year for two consecutive years, the amniocentesis practitioner's approval will be withdrawn. In order to reapprove an Amniocentesis Practitioner after having practitioner approval status withdrawn, the practitioner must perform 5 amniocentesis procedures with on-site supervision in the procedure room by an OB/GYN who is experienced in performing amniocentesis. (Experienced is defined as having performed a minimum of 25 amniocentesis procedures annually on women planning to continue their pregnancies.)

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.

After the second year of low volume, the Consultative Sonologist would become provisional and GDSP would bring the practitioner to the attention of the Perinatal Committee for review. If the practitioner's ultrasound volume continues to be low after the third year, the Consultative Sonologist's approval status will be withdrawn.

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. 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 GDSP.

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 the Perinatal Committee for their recommendations regarding equivalent background and experience. Final decisions are made by the GDSP.

- 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 California licensed Genetic Counselor or Clinical Geneticist. Each approved center must have at least one California licensed Genetic Counselor or one temporary California licensed Genetic Counselor.

1. A Genetic Counselor is defined as:

Having a Genetic Counselor or temporary Genetic Counselor License issued by the California Department of Public Health.

- a. Genetic Counselor Licenses are issued to individuals who have been certified by the American Board of Medical Genetics (ABMG) or American Board of Genetic Counseling (ABGC); or
- b. Temporary Genetic Counselor Licenses are issued to graduates from a Master's Degree, or above, program in genetic counseling from an ABGC or equivalent accredited training program who has Active Candidate Status as defined by the ABGC for the 2013 ABGC certification examination.

Graduates in 2012 or earlier are required to have Active Candidate Status for the 2013 certification examination prior to July 1, 2013.

Graduates in 2013 are required to apply for Active Candidate Status for the 2014 certification examination if they do not apply to sit for the 2013 certification examination.

2. 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.
3. Genetic Counselors with a temporary Genetic Counselor License must attend continuing education courses and/or conferences for 15 hours within a year of being given approval at a PDC.

At least ten of the hours must be from continuing education courses and/or conferences that are granted *Category 1 CEUs* pre-approved by the National Society of Genetic Counselors (NSGC). Only 5 hours of the 15 hours may be from events relevant to a genetic counselor's continuing education and are approved by organizations other than ABGC or NSGC for CEUs or continuing medical education (CME) credits.

4. 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 GDSP 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 GDSP 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 GDSP 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 least 25 CVS procedures, with at least 5 being TC CVS procedures performed annually on women planning to continue their pregnancies.
 4. Any state-approved TC CVS practitioner that provides direct supervision over a Fellow in an ABOG recognized Fellowship Program or another TC CVS practitioner may include any supervised TC CVS procedure(s) toward their annual volume requirement. Only the supervisor would count the procedure(s) towards their annual requirement. Fellows or other supervised TC CVS practitioners are not authorized to perform TC CVS procedures on patients referred through the California Prenatal Screening Program, unless they have Full or Interim Approval as a TC CVS Practitioner.
- 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.
2. 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 GDSP 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.
3. Each of the physicians performing or supervising TA CVS must perform at least 25 CVS procedures (either TC CVS, TA CVS or combination of both), annually on women planning to continue their pregnancies.
4. Any state-approved TA CVS practitioner that provides direct supervision over a Fellow in an ABOG recognized Fellowship Program or another TA CVS practitioner may include any supervised TA CVS procedure(s) toward their annual volume requirement. Only the supervisor would count the procedure(s) towards their annual requirement. Fellows or other supervised TA CVS practitioners are not authorized to perform TA CVS

procedures on patients referred through the California Prenatal Screening Program, unless they have Full or Interim Approval as a TA CVS Practitioner.

- 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.

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 GDSP informing them of their intent to switch affiliations. The original Prenatal Diagnosis Center Director must then submit a letter to the GDSP 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 GDSP 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 GDSP 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 GDSP 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 every six months, 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 performed per year prior to January 1, 2013, less than 25 second trimester amniocentesis procedures performed per year after January 1, 2013, 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 every six months, practitioner approval will be withdrawn. The provisional status will remain in place until the adverse outcome study is completed.

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, at least 25 second trimester amniocentesis procedures per year prior to January 1, 2013, or at least 15 second trimester amniocentesis procedures performed per year after January 1, 2013, 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 Perinatal 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 every six months, practitioner approval will be withdrawn. The provisional status will remain in place until the adverse outcome study is completed.

4. A practitioner requesting a leave of absence for personal reasons or sabbatical leave should submit a letter to the 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 Committee 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.)

- T. Where all state authorized fetal echocardiography is performed by a physician who is accredited or part of a practice accredited with a specialty in fetal echocardiography by the American Institute of Ultrasound in Medicine (AIUM) or by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL).
- U. The application for a new Comprehensive Prenatal Diagnosis Center or a new satellite site has:
 - 1. 30 calendar days to complete the application process, including the submission of all support documentation, from the date of receipt of the application by the GDSP; and,
 - 2. To participate in a State site visit and, within 30 calendar days, successfully meet or resolve any documented findings from the State site visit at which time an approval date will be designated within 7 calendar days; and,
 - 3. 30 calendar days after the designated approval date to be operational to schedule patients;Otherwise the GDSP will consider the application withdrawn.
- V. Any PDC site that has been suspended by the GDSP for failure to meet the PDC Standards will be given 30 calendar days to address any deficiencies; otherwise the site will be closed.

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, S, T, U, and V as described for a Comprehensive Prenatal Diagnosis Center.

Any requests for exceptions to the Standards must be documented in a letter to the GDSP 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 GDSP.

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