

**CALIFORNIA  
HEALTH AND SAFETY CODE SECTION 125050-125119.5**

**125050.** The department shall administer a statewide program for the prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects.

**125055.** The department shall:

**(a)** Establish criteria for eligibility for the prenatal testing program. Eligibility shall include definition of conditions and circumstances that result in a high risk of a detectable genetic disorder or birth defect.

**(b)** Develop an education program designed to educate physicians and surgeons and the public concerning the uses of prenatal testing and the availability of the program.

**(c)** Ensure that genetic counseling be given in conjunction with prenatal testing at the approved prenatal diagnosis centers.

**(d)** Designate sufficient prenatal diagnosis centers to meet the need for these services. Prenatal diagnosis centers shall have equipment and staff trained and capable of providing genetic counseling and performing prenatal diagnostic procedures and tests, including the interpretation of the results of the procedures and tests.

**(e)** Administer a program of subsidy grants for approved nonprofit prenatal diagnosis centers. The subsidy grants shall be awarded based on the reported number of low-income women referred to the center, the number of prenatal diagnoses performed in the previous year at that center, and the estimated size of unmet need for prenatal diagnostic procedures and tests in its service area. This subsidy shall be in addition to fees collected under other state programs.

**(f)** Establish any rules, regulations, and standards for prenatal diagnostic testing and the allocation of subsidies as the director deems necessary to promote and protect the public health and safety and to implement the Hereditary Disorders Act (Section 27).

**(g)**

**(1)** The department shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibit

**(2)** The prenatal screening fee increase for expanding prenatal screening to include those tests described in paragraph (1) is forty dollars (\$40)

**(3)** The department shall report to the Legislature regarding the progress of the program with regard to implementing prenatal screening for those tests described in paragraph (1) on or before July 1, 2007. The report shall include the costs of screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program

**(4)**

**(A)** The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include the expansion of prenatal screenings, pursuant to paragraph (1), may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology

projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.

**(B)(i)** The department may adopt emergency regulations to implement and make specific the amendments to this section made during the 2006 portion of the 2005-06 Regular Session in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Section 11346.1 and Section 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

**(ii)** The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

**125060.** The participation by any individual in the prenatal testing program shall be wholly voluntary and shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participation in, any other program.

**125065.** All prenatal diagnosis centers shall meet standards developed by the department and shall agree to accept patients from state funded or administered programs, including, but not limited to, Medi-Cal, Regional Centers, Maternal and Child Health, California Children's Services, Genetically Handicapped Persons Program, and Family Planning. Only prenatal diagnosis centers meeting standards developed by the department shall be eligible for reimbursement under these state programs.

**125070.** Laboratories licensed by the department shall not offer the maternal serum-alpha fetoprotein screening test for prenatal detection of neural tube defects of the fetus until the department has developed regulations, under the authorization granted by Section 124980. However, laboratories providing this testing, as of July 21, 1983, may continue to provide this testing until these regulations become operative. The department shall adopt regulations pursuant to this section.

**125075.** Every licensed physician and surgeon or other person attending a newborn infant diagnosed as having had rhesus (Rh) isoimmunization hemolytic disease shall report the condition to the department on report forms prescribed by the department.

**125080.** A licensed physician and surgeon or other person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery shall obtain or cause to be obtained a blood specimen of the woman. Prior to obtaining the blood specimen, the woman shall be notified of the fact that the blood specimen is going to be obtained. If the blood specimen is not obtained prior to delivery, it shall be obtained at the time of delivery.

**125085.**

**(a)** As early as possible during prenatal care, a blood specimen obtained pursuant to Section 125080 shall be submitted to a clinical laboratory licensed by the department or to an approved public health laboratory for a determination of rhesus (Rh) blood type and the results shall be reported to both of the following:

- (1)** The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery.
- (2)** The woman tested.

**(b)**

**(1)** In addition, as early as possible during prenatal care, a blood specimen obtained pursuant to Section 125080 shall be submitted to a clinical laboratory licensed by the department or to an approved public health laboratory for a test to determine the presence of hepatitis B surface antigen and the human immunodeficiency virus (HIV), and the results shall be reported to both of the following:

- (A)** The physician and surgeon or other person engaged in the prenatal care of the women or attending the woman at the time of delivery who ordered the test, and who shall subsequently inform the woman tested.
- (B)** A positive test result shall be reported to the local health officer, with the information required and within the timeframes established by the department, pursuant to Chapter 4 (commencing with Section 2500) of Title 17 of the California Code of Regulations.

**(2)** In the event that other tests to determine hepatitis B infection or HIV infection become available, the department may approve additional tests.

**125090.**

**(a)** Subdivision (a) of Section 125085 shall not be applicable if the licensed physician and surgeon or other person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery has knowledge of the woman's blood type and accepts responsibility for the accuracy of the information.

**(b)** Subdivision (b) of Section 125085 shall not be applicable if the licensed physician and surgeon or other person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery has knowledge that the woman has previously been determined to be chronically infected with hepatitis B or human immunodeficiency virus (HIV) and accepts responsibility for the accuracy of the information.

**(c)** Prior to obtaining a blood specimen collected pursuant to subdivision (b) of Section 125085 or this section, the physician and surgeon or other person engaged in the prenatal care of a pregnant woman, or attending the woman at the time of labor or delivery, shall ensure that the woman is informed of the intent to perform a test for HIV infection, the routine nature of the test, the purpose of the testing, the risks and benefits of the test, the risk of perinatal transmission of HIV, that approved treatments are known to decrease the risk of perinatal transmission of HIV, and that the woman has a right to decline this testing.

**(d)** If, during the final review of standard of prenatal care medical tests, the medical records of the pregnant woman do not document a test for rhesus (Rh) antibody blood type, a test for hepatitis B, or a test for HIV, the physician and surgeon or other person engaged in the prenatal care of the woman, or attending the woman at the time of labor or delivery, shall obtain a blood specimen from the woman for the tests that have not been documented. Prior to obtaining this blood specimen, the provider shall ensure that the woman is informed of the intent to perform the tests that have not been documented prior to this visit, including a test for HIV infection, the routine nature of the test, the purpose of the testing, the risks and benefits of the test, the risk of perinatal transmission of HIV, that approved treatments are known to decrease the risk of perinatal transmission of HIV, and that the woman has a right to decline the HIV test. The blood shall be tested by a method that will ensure the earliest possible results, and the results shall be reported to both of the following:

**(1)** The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery.

**(2)** The woman tested.

**(e)** After the results of the tests done pursuant to this section and Section 125085 have been received, the physician and surgeon or other person engaged in the prenatal care of the pregnant woman or attending the woman at the time of labor, delivery, or post partum care at the time the results are received shall ensure that the woman receives information and counseling, as appropriate, to explain the results and the implications for the mother's and infant's health, including any followup testing and care that are indicated.

**(f)** The provisions of Section 125107 for counseling are equally applicable to every pregnant patient covered by subdivisions (c) and (d).

**125095.** The department may adopt regulations as it determines are reasonably necessary for the implementation of the Maternal and Child Health Program Act (Section 27).

**125100.** (a) Clinical laboratories licensed by the department, approved public health laboratories, local health departments, physicians and surgeons, or other persons engaged in the prenatal care of a pregnant woman or in the care of an infant shall maintain and make available to the department information necessary to evaluate, for public health purposes, the effectiveness of testing and followup treatment for the prevention of perinatally transmitted hepatitis B infection.