

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).

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 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 accept or refuse this testing. The acceptance of testing for HIV shall be documented in writing on a form developed by the department and the Office of AIDS pursuant to Section 125092, or on a form that is substantially equivalent in content, and signed by the patient. A copy of this form shall be maintained in the medical record. A multispecialty medical group that provides health care services to enrollees of a health care service plan may use a form incorporating the information in this subdivision and in subdivision (d) instead of any separate form developed pursuant to Section 125092.

(d) If, during the final prenatal care standard medical tests, the medical records of the pregnant woman do not document a test for rhesus (Rh) 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 test that has 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 accept or refuse the HIV test. The acceptance of testing for HIV shall be documented in writing on a form developed by the department and the Office of AIDS, or on a form that is substantially equivalent in content, as described in Section 125092, and signed by the patient. A copy of this form shall be maintained in the medical record. 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 postpartum 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 care that is indicated. If the woman tests positive for HIV antibodies, she shall also receive, whenever possible, a referral to a provider, provider group, or institution specializing in prenatal care for HIV positive women. Health care providers are also strongly encouraged to seek consultation with other providers specializing in the care of pregnant HIV positive women.

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

125092. The department, in consultation with the Office of AIDS and with other stakeholders, including, but not limited to, representatives of professional medical and public health advocacy groups, providers of health care to women and infants infected with or exposed to HIV, and women living with HIV, shall develop culturally sensitive informational material adequate to fulfill the requirements of subdivisions (c) and (d) of Section 125090, in English, Spanish, and other languages used by the department when providing information to clients under the Medi-Cal program. This material shall also include information on available referral and consultation resources of experts in prenatal HIV treatment. This material shall be completed by December 31, 2004.

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.

(b) The department shall make available, to the extent state funds are appropriated therefor in the annual Budget Act or federal funds are available for that purpose, money to each county requesting funds for testing and followup treatment for the prevention of perinatally transmitted hepatitis B infection or for any functions performed pursuant to subdivision (a). The money shall be allocated by the department on the basis of the incidence of perinatally transmitted hepatitis B infection and the need for necessary followup treatment and evaluation in the requesting county.

125105. (a) The blood specimen and test results pursuant to subdivision (b) of Section 125085 shall be confidential and shall not be disclosed, except as otherwise provided by law.

(b) No person shall be compelled in any state, county, city, or other local civil, criminal, administrative, legislative, or other proceeding to provide test results determined pursuant to Section 125080 and Section 125085.

125107. (a) For purposes of this section, "prenatal care provider" means a licensed health care professional providing prenatal care within his or her lawful scope of practice. This definition shall not include a licensed health care professional who provides care other than prenatal care to a pregnant patient.

(b) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall offer human immunodeficiency virus (HIV) information and counseling to every pregnant patient. This information and counseling shall include, but shall not be limited to, all of the following:

(1) A description of the modes of HIV transmission.

(2) A discussion of risk reduction behavior modifications including methods to reduce the risk of perinatal transmission.

(3) If appropriate, referral information to other HIV prevention and psychosocial services including anonymous and confidential test sites approved by the Office of AIDS.

(c) Nothing in this section shall be construed to require mandatory testing. Any documentation or disclosure of HIV related information shall be made in accordance with Chapter 7 (commencing with Section 120975) of Part 4 of Division 105 regarding confidentiality and informed consent.

(d) Notwithstanding Section 125090 or any other provision of law, completion of a statement of acceptance of an HIV test pursuant to Sections 125090 and 125092 shall be sufficient documentation of consent for HIV testing of a pregnant woman or of a woman at the time of labor and delivery, and no laboratory or health care provider shall require any additional written consent or written form as a condition for HIV testing from any woman who is reasonably believed to be pregnant, who is receiving prenatal care, or who is undergoing a panel of tests designated for prenatal patients.

125110. The Maternal and Child Health Program Act (Section 27) shall not apply if the pregnant woman objects to the test required by that act on the ground that the test conflicts with her religious beliefs or practices.

125118. (a) On or before January 1, 2005, the department shall develop guidelines for research involving the derivation or use of human embryonic stem cells in California.

(b) In developing the guidelines specified in subdivision (a), the department may consider other applicable guidelines developed or in use in the United States and in other countries, including, but not limited to, the Guidelines for Research Using Human Pluripotent Stem Cells developed by the National Institutes of Health and published in August 2000, and corrected in November 2000.

(c) The department may contract with a public or private organization, to the extent permitted by state law, for assistance in developing the guidelines.

(d) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends

that date.

125118.5. (a) For purposes of developing the guidelines required by Section 125118, the director shall establish a Human Stem Cell Research Advisory Committee.

(b) The advisory committee shall consist of 13 members, as follows:

(1) Seven scientists with experience in biomedical research in the fields of cell differentiation, nuclear reprogramming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine, or related fields.

(2) Two medical ethicists.

(3) Two persons with backgrounds in legal issues related to human embryonic stem cell research, in vitro fertilization, or family law, as it applies to the donation of embryos and oocytes.

(4) Two persons who are members or leaders of religious organizations.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125119. (a) (1) All research projects involving the derivation or use of human embryonic stem cells shall be reviewed and approved by an institutional review board that is established in accordance with federal regulations, including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations, prior to being undertaken. Any such institutional review board shall, in its review of human embryonic stem cell research projects, consider and apply the guidelines developed by the department pursuant to Section 125118. An institutional review board may require modifications to the plan or design of a proposed human embryonic stem cell research project as a condition of approving the research project.

(2) For purposes of this article, "IRB" means an institutional review board described in paragraph (1).

(b) Not less than once per year, an IRB shall conduct continuing review of human embryonic stem cell research projects reviewed and approved under this section in order to ensure that the research continues to meet the standards for IRB approval. Pursuant to its review in accordance with this subdivision, an IRB may revoke its prior approval of research under this section and require modifications to the plan or design of a continuing research project before permitting the research to continue.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125119.3. (a) Each IRB that has reviewed human embryonic stem cell research pursuant to Section 125119 shall report to the department, annually, on the number of human embryonic stem cell research projects that the IRB has reviewed, and the status and disposition of each of those projects.

(b) Each IRB shall also report to the department regarding unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance with the requirements or determinations of

the IRB with respect to the review of human embryonic stem cell research projects, and the actions taken by the IRB to respond to these situations.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125119.5. (a) The department shall at least annually review reports from IRBs pursuant to Section 125120, and may revise the guidelines developed pursuant to Section 125118, as it deems necessary.

(b) The department shall report annually to the Legislature on human embryonic stem cell research activity. These annual reports shall be compiled from the reports from IRBs pursuant to Section 125120.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.
