

Assembly Bill No. 395

Passed the Assembly June 1, 2011

Chief Clerk of the Assembly

Passed the Senate August 31, 2011

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2011, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 124977 and 125001 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 395, Pan. Newborn screening program.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing.

Existing law establishes the continuously appropriated Genetic Disease Testing Fund (GDTF), consisting of fees paid for newborn screening tests. Existing law states the intent of the Legislature that all costs of the genetic disease testing program be fully supported by fees paid for newborn screening tests, which are deposited in the GDTF. Existing law also authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis and biotinidase and exempts the expansion of contracts for this purpose from certain provisions of the Public Contract Code, the Government Code, and the State Administrative Manual, as specified.

This bill would require the department to expand statewide screening of newborns to include screening for severe combined immunodeficiency (SCID) and, insofar as it does not require additional costs, other T-cell lymphopenias detectable as a result of screening for SCID, and would make related changes.

The people of the State of California do enact as follows:

SECTION 1. Section 124977 of the Health and Safety Code is amended to read:

124977. (a) It is the intent of the Legislature that, unless otherwise specified, the genetic disease testing program carried out pursuant to this chapter be fully supported from fees collected for services provided by the program.

(b) (1) The department shall charge a fee to all payers for any tests or activities performed pursuant to this chapter. The amount

of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter. Notwithstanding any other provision of law, any fees charged for prenatal screening and followup services provided to persons enrolled in the Medi-Cal program, health care service plan enrollees, or persons covered by health insurance policies, shall be paid in full and deposited in the Genetic Disease Testing Fund or the Birth Defects Monitoring Fund consistent with this section, subject to all terms and conditions of each enrollee's or insured's health care service plan or insurance coverage, whichever is applicable, including, but not limited to, copayments and deductibles applicable to these services, and only if these copayments, deductibles, or limitations are disclosed to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(2) The department shall expeditiously undertake all steps necessary to implement the fee collection process, including personnel, contracts, and data processing, so as to initiate the fee collection process at the earliest opportunity.

(3) Effective for services provided on and after July 1, 2002, the department shall charge a fee to the hospital of birth, or, for births not occurring in a hospital, to families of the newborn, for newborn screening and followup services. The hospital of birth and families of newborns born outside the hospital shall make payment in full to the Genetic Disease Testing Fund. The department shall not charge or bill Medi-Cal beneficiaries for services provided under this chapter.

(4) (A) The department shall charge a fee for prenatal screening to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program.

(B) The prenatal screening fee for activities of the Birth Defects Monitoring Program shall be ten dollars (\$10).

(5) The department shall set guidelines for invoicing, charging, and collecting from approved researchers the amount necessary to cover all expenses associated with research application requests made under this section, data linkage, retrieval, data processing, data entry, reinventory, and shipping of blood samples or their components and related data management.

(6) The only funds from the Genetic Disease Testing Fund that may be used for the purpose of supporting the pregnancy blood

sample storage, testing, and research activities of the Birth Defects Monitoring Program are those prenatal screening fees assessed and collected prior to the creation of the Birth Defects Monitoring Program Fund specifically to support those Birth Defects Monitoring Program activities.

(7) The Birth Defects Monitoring Program Fund is hereby created as a special fund in the State Treasury. Fee revenues that are collected pursuant to paragraph (4) shall be deposited into the fund and shall be available upon appropriation by the Legislature to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program. Notwithstanding Section 16305.7 of the Government Code, interest earned on funds in the Birth Defects Monitoring Program Fund shall be deposited as revenue into the fund to support the Birth Defects Monitoring Program.

(c) (1) The Legislature finds that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory and administrative procedures to obtain the most cost-effective electronic data processing, hardware, software services, testing equipment, and testing and followup services.

(2) The expenditure of funds from the Genetic Disease Testing Fund for these purposes shall not be subject to Section 12102 of, and Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of, the Public Contract Code, or to Division 25.2 (commencing with Section 38070). The department shall provide the Department of Finance with documentation that equipment and services have been obtained at the lowest cost consistent with technical requirements for a comprehensive high-quality program.

(3) The expenditure of funds from the Genetic Disease Testing Fund for implementation of the Tandem Mass Spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders, and screening for congenital adrenal hyperplasia may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts and shall not be subject to 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, and any policies, procedures, regulations or manuals authorized by those laws.

(4) The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, and severe combined immunodeficiency (SCID) 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.

(d) (1) The department may adopt emergency regulations to implement and make specific this chapter 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 Sections 11346.1 and 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.

(2) 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.

(3) The Legislature finds and declares that the health and safety of California newborns is in part dependent on an effective and adequately staffed genetic disease program, the cost of which shall be supported by the fees generated by the program.

SEC. 2. Section 125001 of the Health and Safety Code is amended to read:

125001. (a) The department shall establish a program for the development, provision, and evaluation of genetic disease testing, and may provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. The program shall provide genetic screening and followup services for persons who have the screening.

(b) The department shall expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and congenital adrenal hyperplasia as soon as possible. The department shall provide information with respect to these disorders and available testing resources to all women receiving prenatal care and to all women admitted to a hospital for delivery. If the department is unable to provide this statewide screening by August 1, 2005, the department shall temporarily obtain these testing services through a competitive bid process from one or more public or private laboratories that meet the department's requirements for testing, quality assurance, and reporting. If the department determines that contracting for these services is more cost-effective, and meets the other requirements of this chapter, than purchasing the tandem mass spectrometry equipment themselves, the department shall contract with one or more public or private laboratories.

(c) The department shall expand statewide screening of newborns to include screening for severe combined immunodeficiency (SCID) as soon as possible. In implementing the SCID screening test, the department shall also screen for other T-cell lymphopenias that are detectable as a result of screening

for SCID, insofar as it does not require additional costs or equipment beyond that needed to test for SCID.

Approved _____, 2011

Governor