

AMENDED IN ASSEMBLY APRIL 7, 2011  
AMENDED IN ASSEMBLY MARCH 31, 2011  
CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

**ASSEMBLY BILL**

**No. 395**

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**Introduced by Assembly Member Pan**

February 14, 2011

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An act to amend Sections 124977 and ~~125000~~ 125001 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 395, as amended, Pan. Newborn screening program.

Existing law requires the ~~genetic disease unit within the State Department of Public Health to promote a statewide program of information, testing, and counseling services to detect specified heritable disorders~~ *establish a program for the development, provision, and evaluation of genetic disease testing*. Existing law requires the ~~genetic disease unit to evaluate and prepare recommendations on the implementation of tests for the detection of hereditary and congenital diseases, as specified.~~

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 ~~add~~ require the department to expand statewide screening of newborns to include screening for severe combined immuno deficiency immunodeficiency (SCID) ~~to the list of diseases for which the genetic disease unit is required to evaluate and prepare recommendations~~ and would make related changes.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

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

3 124977. (a) It is the intent of the Legislature that, unless  
4 otherwise specified, the genetic disease testing program carried  
5 out pursuant to this chapter be fully supported from fees collected  
6 for services provided by the program.

7 (b) (1) The department shall charge a fee to all payers for any  
8 tests or activities performed pursuant to this chapter. The amount  
9 of the fee shall be established by regulation and periodically  
10 adjusted by the director in order to meet the costs of this chapter.  
11 Notwithstanding any other provision of law, any fees charged for  
12 prenatal screening and followup services provided to persons  
13 enrolled in the Medi-Cal program, health care service plan  
14 enrollees, or persons covered by health insurance policies, shall  
15 be paid in full and deposited in the Genetic Disease Testing Fund  
16 or the Birth Defects Monitoring Fund consistent with this section,  
17 subject to all terms and conditions of each enrollee's or insured's  
18 health care service plan or insurance coverage, whichever is  
19 applicable, including, but not limited to, copayments and  
20 deductibles applicable to these services, and only if these  
21 copayments, deductibles, or limitations are disclosed to the  
22 subscriber or enrollee pursuant to the disclosure provisions of  
23 Section 1363.

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

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

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

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

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

20 (6) The only funds from the Genetic Disease Testing Fund that  
21 may be used for the purpose of supporting the pregnancy blood  
22 sample storage, testing, and research activities of the Birth Defects  
23 Monitoring Program are those prenatal screening fees assessed  
24 and collected prior to the creation of the Birth Defects Monitoring  
25 Program Fund specifically to support those Birth Defects  
26 Monitoring Program activities.

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

37 (c) (1) The Legislature finds that timely implementation of  
38 changes in genetic screening programs and continuous maintenance  
39 of quality statewide services requires expeditious regulatory and  
40 administrative procedures to obtain the most cost-effective

1 electronic data processing, hardware, software services, testing  
2 equipment, and testing and followup services.

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

11 (3) The expenditure of funds from the Genetic Disease Testing  
12 Fund for implementation of the Tandem Mass Spectrometry  
13 screening for fatty acid oxidation, amino acid, and organic acid  
14 disorders, and screening for congenital adrenal hyperplasia may  
15 be implemented through the amendment of the Genetic Disease  
16 Branch Screening Information System contracts and shall not be  
17 subject to Chapter 3 (commencing with Section 12100) of Part 2  
18 of Division 2 of the Public Contract Code, Article 4 (commencing  
19 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title  
20 2 of the Government Code, and any policies, procedures,  
21 regulations or manuals authorized by those laws.

22 (4) The expenditure of funds from the Genetic Disease Testing  
23 Fund for the expansion of the Genetic Disease Branch Screening  
24 Information System to include cystic fibrosis, biotinidase, and  
25 severe combined ~~immuno~~-deficiency *immunodeficiency* (SCID)  
26 may be implemented through the amendment of the Genetic  
27 Disease Branch Screening Information System contracts, and shall  
28 not be subject to Chapter 2 (commencing with Section 10290) or  
29 Chapter 3 (commencing with Section 12100) of Part 2 of Division  
30 2 of the Public Contract Code, Article 4 (commencing with Section  
31 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the  
32 Government Code, or Sections 4800 to 5180, inclusive, of the  
33 State Administrative Manual as they relate to approval of  
34 information technology projects or approval of increases in the  
35 duration or costs of information technology projects. This  
36 paragraph shall apply to the design, development, and  
37 implementation of the expansion, and to the maintenance and  
38 operation of the Genetic Disease Branch Screening Information  
39 System, including change requests, once the expansion is  
40 implemented.

1 (d) (1) The department may adopt emergency regulations to  
2 implement and make specific this chapter in accordance with  
3 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division  
4 3 of Title 2 of the Government Code. For the purposes of the  
5 Administrative Procedure Act, the adoption of regulations shall  
6 be deemed an emergency and necessary for the immediate  
7 preservation of the public peace, health and safety, or general  
8 welfare. Notwithstanding Chapter 3.5 (commencing with Section  
9 11340) of Part 1 of Division 3 of Title 2 of the Government Code,  
10 these emergency regulations shall not be subject to the review and  
11 approval of the Office of Administrative Law. Notwithstanding  
12 Sections 11346.1 and 11349.6 of the Government Code, the  
13 department shall submit these regulations directly to the Secretary  
14 of State for filing. The regulations shall become effective  
15 immediately upon filing by the Secretary of State. Regulations  
16 shall be subject to public hearing within 120 days of filing with  
17 the Secretary of State and shall comply with Sections 11346.8 and  
18 11346.9 of the Government Code or shall be repealed.

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

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

30 ~~SEC. 2. Section 125000 of the Health and Safety Code is~~  
31 ~~amended to read:~~

32 ~~125000. (a) It is the policy of the State of California to make~~  
33 ~~every effort to detect, as early as possible, phenylketonuria and~~  
34 ~~other preventable heritable or congenital disorders leading to~~  
35 ~~mental retardation or physical defects.~~

36 ~~The department shall establish a genetic disease unit, that shall~~  
37 ~~coordinate all programs of the department in the area of genetic~~  
38 ~~disease. The unit shall promote a statewide program of information,~~  
39 ~~testing, and counseling services and shall have the responsibility~~

1 of designating tests and regulations to be used in executing this  
2 program.

3 The information, tests, and counseling for children shall be in  
4 accordance with accepted medical practices and shall be  
5 administered to each child born in California once the department  
6 has established appropriate regulations and testing methods. The  
7 information, tests, and counseling for pregnant women shall be in  
8 accordance with accepted medical practices and shall be offered  
9 to each pregnant woman in California once the department has  
10 established appropriate regulations and testing methods. These  
11 regulations shall follow the standards and principles specified in  
12 Section 124980. The department may provide laboratory testing  
13 facilities or contract with any laboratory that it deems qualified to  
14 conduct tests required under this section. However, notwithstanding  
15 Section 125005, provision of laboratory testing facilities by the  
16 department shall be contingent upon the provision of funding  
17 therefor by specific appropriation to the Genetic Disease Testing  
18 Fund enacted by the Legislature. If moneys appropriated for  
19 purposes of this section are not authorized for expenditure to  
20 provide laboratory facilities, the department may nevertheless  
21 contract to provide laboratory testing services pursuant to this  
22 section and shall perform laboratory services, including, but not  
23 limited to, quality control, confirmatory, and emergency testing,  
24 necessary to ensure the objectives of this program.

25 (b) The department shall charge a fee for any tests performed  
26 pursuant to this section. The amount of the fee shall be established  
27 and periodically adjusted by the director in order to meet the costs  
28 of this section.

29 (c) The department shall inform all hospitals or physicians and  
30 surgeons, or both, of required regulations and tests and may alter  
31 or withdraw any of these requirements whenever sound medical  
32 practice so indicates. To the extent practicable, the department  
33 shall provide notice to hospitals and other payers in advance of  
34 any increase in the fees charged for the program.

35 (d) This section shall not apply if a parent or guardian of the  
36 newborn child objects to a test on the ground that the test conflicts  
37 with his or her religious beliefs or practices.

38 (e) The genetic disease unit is authorized to make grants or  
39 contracts or payments to vendors approved by the department for  
40 all of the following:

1 ~~(1) Testing and counseling services.~~

2 ~~(2) Demonstration projects to determine the desirability and~~  
3 ~~feasibility of additional tests or new genetic services.~~

4 ~~(3) To initiate the development of genetic services in areas of~~  
5 ~~need.~~

6 ~~(4) To purchase or provide genetic services from any sums as~~  
7 ~~are appropriated for this purpose.~~

8 ~~(f) The genetic disease unit shall evaluate and prepare~~  
9 ~~recommendations on the implementation of tests for the detection~~  
10 ~~of hereditary and congenital diseases, including, but not limited~~  
11 ~~to, biotinidase deficiency, severe combined immuno deficiency~~  
12 ~~(SCID), and cystic fibrosis. The genetic disease unit shall also~~  
13 ~~evaluate and prepare recommendations on the availability and~~  
14 ~~effectiveness of preventative followup interventions, including the~~  
15 ~~use of specialized medically necessary dietary products.~~

16 ~~It is the intent of the Legislature that funds for the support of the~~  
17 ~~evaluations and recommendations required pursuant to this~~  
18 ~~subdivision, including, but not limited to, costs associated with~~  
19 ~~the expansion and ongoing administration required to test for SCID,~~  
20 ~~and for the activities authorized pursuant to subdivision (e), shall~~  
21 ~~be provided in the annual Budget Act appropriation from the~~  
22 ~~Genetic Disease Testing Fund.~~

23 ~~(g) Health care providers that contract with a prepaid group~~  
24 ~~practice health care service plan that annually has at least 20,000~~  
25 ~~births among its membership, may provide, without contracting~~  
26 ~~with the department, any or all of the testing and counseling~~  
27 ~~services required to be provided under this section or the~~  
28 ~~regulations adopted pursuant thereto, if the services meet the~~  
29 ~~quality standards and adhere to the regulations established by the~~  
30 ~~department and the plan pays that portion of a fee established under~~  
31 ~~this section that is directly attributable to the department's cost of~~  
32 ~~administering the testing or counseling service and to any required~~  
33 ~~testing or counseling services provided by the state for plan~~  
34 ~~members. The payment by the plan, as provided in this subdivision,~~  
35 ~~shall be deemed to fulfill any obligation the provider or the~~  
36 ~~provider's patient may have to the department to pay a fee in~~  
37 ~~connection with the testing or counseling service.~~

38 ~~(h) The department may appoint experts in the area of genetic~~  
39 ~~screening, including, but not limited to, cytogenetics, molecular~~  
40 ~~biology, prenatal, specimen collection, and ultrasound to provide~~

1 expert advice and opinion on the interpretation and enforcement  
2 of regulations adopted pursuant to this section. These experts shall  
3 be designated agents of the state with respect to their assignments.  
4 These experts shall receive no salary, but shall be reimbursed for  
5 expenses associated with the purposes of this section. All expenses  
6 of the experts for the purposes of this section shall be paid from  
7 the Genetic Disease Testing Fund.

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

10 125001. (a) The department shall establish a program for the  
11 development, provision, and evaluation of genetic disease testing,  
12 and may provide laboratory testing facilities or make grants to,  
13 contract with, or make payments to, any laboratory that it deems  
14 qualified and cost-effective to conduct testing or with any  
15 metabolic specialty clinic to provide necessary treatment with  
16 qualified specialists. The program shall provide genetic screening  
17 and followup services for persons who have the screening.

18 (b) The department shall expand statewide screening of  
19 newborns to include tandem mass spectrometry screening for fatty  
20 acid oxidation, amino acid, and organic acid disorders and  
21 congenital adrenal hyperplasia as soon as possible. The department  
22 shall provide information with respect to these disorders and  
23 available testing resources to all women receiving prenatal care  
24 and to all women admitted to a hospital for delivery. If the  
25 department is unable to provide this statewide screening by August  
26 1, 2005, the department shall temporarily obtain these testing  
27 services through a competitive bid process from one or more public  
28 or private laboratories that meet the department's requirements  
29 for testing, quality assurance, and reporting. If the department  
30 determines that contracting for these services is more cost-effective,  
31 and meets the other requirements of this chapter, than purchasing  
32 the tandem mass spectrometry equipment themselves, the  
33 department shall contract with one or more public or private  
34 laboratories.

35 (c) *The department shall expand statewide screening of*  
36 *newborns to include screening for severe combined*  
37 *immunodeficiency (SCID) as soon as possible.*

38 (e) ~~The department shall report to the Legislature regarding the~~  
39 ~~progress of the program on or before July 1, 2006. The report shall~~  
40 ~~include the costs for screening, followup, and treatment as~~

- 1 compared to costs and morbidity averted for each condition tested
- 2 for in the program.

O