

AMENDED IN ASSEMBLY AUGUST 1, 2016

AMENDED IN SENATE MAY 31, 2016

**SENATE BILL**

**No. 1095**

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**Introduced by Senator Pan**

**(Coauthors: Senators Beall, McGuire, and Nielsen)**

*(Coauthors: Assembly Members Chiu, Gomez, Maienschein, and Rodriguez)*

February 17, 2016

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

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, as amended, 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, and 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, biotinidase, severe combined immunodeficiency (SCID), and adrenoleukodystrophy (ALD) 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 any disease that is detectable in blood samples as soon as the disease is adopted by the federal Recommended Uniform Screening Panel (RUSP). By expanding the purposes for which moneys from the ~~fund~~ *GDTF* may be expended, this bill would make an appropriation.

Vote: majority. Appropriation: yes. 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 law, any fees charged for prenatal  
12 screening and followup services provided to persons enrolled in  
13 the Medi-Cal program, health care service plan enrollees, or  
14 persons covered by health insurance policies, shall be paid in full  
15 and deposited in the Genetic Disease Testing Fund or the Birth  
16 Defects Monitoring Program Fund consistent with this section.

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

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

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

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

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

12 (6) The only funds from the Genetic Disease Testing Fund that  
13 may be used for the purpose of supporting the pregnancy blood  
14 sample storage, testing, and research activities of the Birth Defects  
15 Monitoring Program are those prenatal screening fees assessed  
16 and collected prior to the creation of the Birth Defects Monitoring  
17 Program Fund specifically to support those Birth Defects  
18 Monitoring Program activities.

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

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

35 (2) The expenditure of funds from the Genetic Disease Testing  
36 Fund for these purposes shall not be subject to Section 12102 of,  
37 and Chapter 2 (commencing with Section 10290) of Part 2 of  
38 Division 2 of, the Public Contract Code, or to Division 25.2  
39 (commencing with Section 38070) of this code. The department  
40 shall provide the Department of Finance with documentation that

1 equipment and services have been obtained at the lowest cost  
2 consistent with technical requirements for a comprehensive  
3 high-quality program.

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

15 (4) The expenditure of funds from the Genetic Disease Testing  
16 Fund for the expansion of the Genetic Disease Branch Screening  
17 Information System to include cystic fibrosis, biotinidase, severe  
18 combined immunodeficiency (SCID), adrenoleukodystrophy  
19 (ALD), and any other disease that is detectable in blood samples,  
20 as specified in subdivision (d) of Section 125001, may be  
21 implemented through the amendment of the Genetic Disease  
22 Branch Screening Information System contracts, and shall not be  
23 subject to Chapter 2 (commencing with Section 10290) or Chapter  
24 3 (commencing with Section 12100) of Part 2 of Division 2 of the  
25 Public Contract Code, Article 4 (commencing with Section 19130)  
26 of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government  
27 Code, or Sections 4800 to 5180, inclusive, of the State  
28 Administrative Manual as they relate to approval of information  
29 technology projects or approval of increases in the duration or  
30 costs of information technology projects. This paragraph shall  
31 apply to the design, development, and implementation of the  
32 expansion, and to the maintenance and operation of the Genetic  
33 Disease Branch Screening Information System, including change  
34 requests, once the expansion is implemented.

35 (d) (1) The department may adopt emergency regulations to  
36 implement and make specific this chapter in accordance with  
37 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division  
38 3 of Title 2 of the Government Code. For the purposes of the  
39 Administrative Procedure Act, the adoption of regulations shall  
40 be deemed an emergency and necessary for the immediate

1 preservation of the public peace, health and safety, or general  
2 welfare. Notwithstanding Chapter 3.5 (commencing with Section  
3 11340) of Part 1 of Division 3 of Title 2 of the Government Code,  
4 these emergency regulations shall not be subject to the review and  
5 approval of the Office of Administrative Law. Notwithstanding  
6 Sections 11346.1 and 11349.6 of the Government Code, the  
7 department shall submit these regulations directly to the Secretary  
8 of State for filing. The regulations shall become effective  
9 immediately upon filing by the Secretary of State. Regulations  
10 shall be subject to public hearing within 120 days of filing with  
11 the Secretary of State and shall comply with Sections 11346.8 and  
12 11346.9 of the Government Code or shall be repealed.

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

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

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

26 125001. (a) The department shall establish a program for the  
27 development, provision, and evaluation of genetic disease testing,  
28 and may provide laboratory testing facilities or make grants to,  
29 contract with, or make payments to, any laboratory that it deems  
30 qualified and cost effective to conduct testing or with any metabolic  
31 specialty clinic to provide necessary treatment with qualified  
32 specialists. The program shall provide genetic screening and  
33 followup services for persons who have the screening.

34 (b) The department shall expand statewide screening of  
35 newborns to include tandem mass spectrometry screening for fatty  
36 acid oxidation, amino acid, organic acid disorders, and congenital  
37 adrenal hyperplasia as soon as possible. The department shall  
38 provide information with respect to these disorders and available  
39 testing resources to all women receiving prenatal care and to all  
40 women admitted to a hospital for delivery. If the department is

1 unable to provide this statewide screening by August 1, 2005, the  
2 department shall temporarily obtain these testing services through  
3 a competitive bid process from one or more public or private  
4 laboratories that meet the department's requirements for testing,  
5 quality assurance, and reporting. If the department determines that  
6 contracting for these services is more cost effective, and meets the  
7 other requirements of this chapter, than purchasing the tandem  
8 mass spectrometry equipment themselves, the department shall  
9 contract with one or more public or private laboratories.

10 (c) The department shall expand statewide screening of  
11 newborns to include screening for severe combined  
12 immunodeficiency (SCID) as soon as possible. In implementing  
13 the SCID screening test, the department shall also screen for other  
14 T-cell lymphopenias that are detectable as a result of screening  
15 for SCID, insofar as it does not require additional costs or  
16 equipment beyond that needed to test for SCID.

17 (d) The department shall expand statewide screening of  
18 newborns to include screening for adrenoleukodystrophy (ALD)  
19 and any other disease that is detectable in blood samples as soon  
20 as the disease is adopted by the federal Recommended Uniform  
21 Screening Panel (RUSP).