

AMENDED IN ASSEMBLY MARCH 19, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1559**

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**Introduced by Assembly Member Pan**  
*(Principal coauthor: Assembly Member Fox)*  
**(Coauthors: Assembly Members Bloom, Brown, Chesbro,**  
**Maienschein, Nazarian, and Wieckowski)**  
(Coauthors: Senators Fuller, Hill, *Vidak*, and Wyland)

January 28, 2014

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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

AB 1559, 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, and severe combined immunodeficiency (SCID) 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 adrenoleukodystrophy (ALD). By expanding the purposes for which moneys from the fund 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 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.

28 (3) Effective for services provided on and after July 1, 2002,  
29 the department shall charge a fee to the hospital of birth, or, for  
30 births not occurring in a hospital, to families of the newborn, for  
31 newborn screening and followup services. The hospital of birth

1 and families of newborns born outside the hospital shall make  
2 payment in full to the Genetic Disease Testing Fund. The  
3 department shall not charge or bill Medi-Cal beneficiaries for  
4 services provided under this chapter.

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

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

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

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

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

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

39 (2) The expenditure of funds from the Genetic Disease Testing  
40 Fund for these purposes shall not be subject to Section 12102 of,

1 and Chapter 2 (commencing with Section 10290) of Part 2 of  
2 Division 2 of, the Public Contract Code, or to Division 25.2  
3 (commencing with Section 38070). The department shall provide  
4 the Department of Finance with documentation that equipment  
5 and services have been obtained at the lowest cost consistent with  
6 technical requirements for a comprehensive high-quality program.

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

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

37 (d) (1) The department may adopt emergency regulations to  
38 implement and make specific this chapter in accordance with  
39 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division  
40 3 of Title 2 of the Government Code. For the purposes of the

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

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

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

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

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

36 (b) The department shall expand statewide screening of  
37 newborns to include tandem mass spectrometry screening for fatty  
38 acid oxidation, amino acid, ~~and~~ organic acid disorders, and  
39 congenital adrenal hyperplasia as soon as possible. The department  
40 shall provide information with respect to these disorders and

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

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

20 (d) The department shall expand statewide screening of  
21 newborns to include screening for adrenoleukodystrophy (ALD)  
22 as soon as possible.