

AMENDED IN SENATE AUGUST 19, 2014

AMENDED IN ASSEMBLY MAY 23, 2014

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 coauthors: Assembly Members Fox and Gatto)**  
**(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, *repeal, and add* 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, *until January 1, 2018*, 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 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 Fund consistent with this section, subject to  
17 all terms and conditions of each enrollee's or insured's health care  
18 service plan or insurance coverage, whichever is applicable,  
19 including, but not limited to, copayments and deductibles  
20 applicable to these services, and only if these copayments,  
21 deductibles, or limitations are disclosed to the subscriber or enrollee  
22 pursuant to the disclosure provisions of Section 1363.  
23 (2) The department shall expeditiously undertake all steps  
24 necessary to implement the fee collection process, including  
25 personnel, contracts, and data processing, so as to initiate the fee  
26 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, severe  
25 combined immunodeficiency (SCID), and adrenoleukodystrophy  
26 (ALD) 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 (e) *This section shall remain in effect only until January 1, 2018,*  
31 *and as of that date is repealed, unless a later enacted statute, that*  
32 *is enacted before January 1, 2018, deletes or extends that date.*

33 *SEC. 2. Section 124977 is added to the Health and Safety Code,*  
34 *to read:*

35 *124977. (a) It is the intent of the Legislature that, unless*  
36 *otherwise specified, the genetic disease testing program carried*  
37 *out pursuant to this chapter be fully supported from fees collected*  
38 *for services provided by the program.*

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

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

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

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

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

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

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

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

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

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

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

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

30 (3) *The expenditure of funds from the Genetic Disease Testing*  
31 *Fund for implementation of the Tandem Mass Spectrometry*  
32 *screening for fatty acid oxidation, amino acid, and organic acid*  
33 *disorders, and screening for congenital adrenal hyperplasia may*  
34 *be implemented through the amendment of the Genetic Disease*  
35 *Branch Screening Information System contracts and shall not be*  
36 *subject to Chapter 3 (commencing with Section 12100) of Part 2*  
37 *of Division 2 of the Public Contract Code, Article 4 (commencing*  
38 *with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title*  
39 *2 of the Government Code, and any policies, procedures,*  
40 *regulations or manuals authorized by those laws.*

1     (4) *The expenditure of funds from the Genetic Disease Testing*  
2 *Fund for the expansion of the Genetic Disease Branch Screening*  
3 *Information System to include cystic fibrosis, biotinidase, and*  
4 *severe combined immunodeficiency (SCID) may be implemented*  
5 *through the amendment of the Genetic Disease Branch Screening*  
6 *Information System contracts, and shall not be subject to Chapter*  
7 *2 (commencing with Section 10290) or Chapter 3 (commencing*  
8 *with Section 12100) of Part 2 of Division 2 of the Public Contract*  
9 *Code, Article 4 (commencing with Section 19130) of Chapter 5 of*  
10 *Part 2 of Division 5 of Title 2 of the Government Code, or Sections*  
11 *4800 to 5180, inclusive, of the State Administrative Manual as*  
12 *they relate to approval of information technology projects or*  
13 *approval of increases in the duration or costs of information*  
14 *technology projects. This paragraph shall apply to the design,*  
15 *development, and implementation of the expansion, and to the*  
16 *maintenance and operation of the Genetic Disease Branch*  
17 *Screening Information System, including change requests, once*  
18 *the expansion is implemented.*

19     (d) (1) *The department may adopt emergency regulations to*  
20 *implement and make specific this chapter in accordance with*  
21 *Chapter 3.5 (commencing with Section 11340) of Part 1 of Division*  
22 *3 of Title 2 of the Government Code. For the purposes of the*  
23 *Administrative Procedure Act, the adoption of regulations shall*  
24 *be deemed an emergency and necessary for the immediate*  
25 *preservation of the public peace, health and safety, or general*  
26 *welfare. Notwithstanding Chapter 3.5 (commencing with Section*  
27 *11340) of Part 1 of Division 3 of Title 2 of the Government Code,*  
28 *these emergency regulations shall not be subject to the review and*  
29 *approval of the Office of Administrative Law. Notwithstanding*  
30 *Sections 11346.1 and 11349.6 of the Government Code, the*  
31 *department shall submit these regulations directly to the Secretary*  
32 *of State for filing. The regulations shall become effective*  
33 *immediately upon filing by the Secretary of State. Regulations*  
34 *shall be subject to public hearing within 120 days of filing with*  
35 *the Secretary of State and shall comply with Sections 11346.8 and*  
36 *11346.9 of the Government Code or shall be repealed.*

37     (2) *The Office of Administrative Law shall provide for the*  
38 *printing and publication of these regulations in the California*  
39 *Code of Regulations. Notwithstanding Chapter 3.5 (commencing*  
40 *with Section 11340) of Part 1 of Division 3 of Title 2 of the*

1 *Government Code, the regulations adopted pursuant to this chapter*  
2 *shall not be repealed by the Office of Administrative Law and shall*  
3 *remain in effect until revised or repealed by the department.*

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

8 *(e) This section shall become operative on January 1, 2018.*

9 ~~SEC. 2.~~

10 *SEC. 3.* Section 125001 of the Health and Safety Code is  
11 amended to read:

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

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

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

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

3 (d) The department shall expand statewide screening of  
4 newborns to include screening for adrenoleukodystrophy (ALD)  
5 as soon as possible.

6 (e) *This section shall remain in effect only until January 1, 2018,*  
7 *and as of that date is repealed, unless a later enacted statute, that*  
8 *is enacted before January 1, 2018, deletes or extends that date.*

9 SEC. 4. *Section 125001 is added to the Health and Safety Code,*  
10 *to read:*

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

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

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

- 1 *for SCID, insofar as it does not require additional costs or*
- 2 *equipment beyond that needed to test for SCID.*
- 3 *(d) This section shall become operative on January 1, 2018.*

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