

AMENDED IN SENATE APRIL 24, 2012

AMENDED IN SENATE APRIL 12, 2012

**SENATE BILL**

**No. 1072**

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**Introduced by Senator Strickland**  
**(~~Coauthor: Senator~~ *Coauthors: Senators Anderson and Walters*)**  
(Coauthor: Assembly Member Portantino)

February 14, 2012

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

LEGISLATIVE COUNSEL'S DIGEST

SB 1072, as amended, Strickland. 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 authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System, as specified, to include cystic fibrosis, biotinidase, and severe combined immunodeficiency. Existing law exempts the amendment of contracts for this purpose from provisions of the Public Contract Code that establish standards for contracts and require the Department of General Services to approve these contracts. Existing law also exempts the amendment of contracts for this purpose from standards for personal services contracts and from provisions that give the California

Technology Agency authority over the application of information technology for state agencies.

This bill would require the department, *until January 1, 2018*, to expand statewide screening of newborns to include screening for 6 2 types of lysosomal storage diseases, *Hurler syndrome and Krabbe disease*, and would exempt the amendment of contracts for this purpose from provisions that establish standards for contracts, require the Department of General Services to approve contracts, and give the California Technology Agency authority over information technology projects, as described above.

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. This act shall be known, and may be cited, as  
2 Jacquelyn's Bill.

3 SEC. 2. Section 124977 of the Health and Safety Code is  
4 amended to read:

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

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

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

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

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

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

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

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

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

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

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

15 (3) The expenditure of funds from the Genetic Disease Testing  
16 Fund for implementation of the tandem mass spectrometry  
17 screening for fatty acid oxidation, amino acid, and organic acid  
18 disorders, and screening for congenital adrenal hyperplasia may  
19 be implemented through the amendment of the Genetic Disease  
20 Branch Screening Information System contracts and shall not be  
21 subject to Chapter 3 (commencing with Section 12100) of Part 2  
22 of Division 2 of the Public Contract Code, Article 4 (commencing  
23 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title  
24 2 of the Government Code, and any policies, procedures,  
25 regulations, or manuals authorized by those laws.

26 (4) The expenditure of funds from the Genetic Disease Testing  
27 Fund for the expansion of the Genetic Disease Branch Screening  
28 Information System to include cystic fibrosis, biotinidase, severe  
29 combined immunodeficiency (SCID), *Hurler syndrome, also known*  
30 *as mucopolysaccharidosis type I (MPSI), and ~~lysosomal storage~~*  
31 *diseases Krabbe disease* may be implemented through the  
32 amendment of the Genetic Disease Branch Screening Information  
33 System contracts, and shall not be subject to Chapter 2  
34 (commencing with Section 10290) or Chapter 3 (commencing with  
35 Section 12100) of Part 2 of Division 2 of the Public Contract Code,  
36 Article 4 (commencing with Section 19130) of Chapter 5 of Part  
37 2 of Division 5 of Title 2 of the Government Code, or Sections  
38 4800 to 5180, inclusive, of the State Administrative Manual as  
39 they relate to approval of information technology projects or  
40 approval of increases in the duration or costs of information

1 technology projects. This paragraph shall apply to the design,  
2 development, and implementation of the expansion, and to the  
3 maintenance and operation of the Genetic Disease Branch  
4 Screening Information System, including change requests, once  
5 the expansion is implemented.

6 (d) (1) The department may adopt emergency regulations to  
7 implement and make specific this chapter in accordance with  
8 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division  
9 3 of Title 2 of the Government Code. For the purposes of the  
10 Administrative Procedure Act, the adoption of regulations shall  
11 be deemed an emergency and necessary for the immediate  
12 preservation of the public peace, health and safety, or general  
13 welfare. Notwithstanding Chapter 3.5 (commencing with Section  
14 11340) of Part 1 of Division 3 of Title 2 of the Government Code,  
15 these emergency regulations shall not be subject to the review and  
16 approval of the Office of Administrative Law. Notwithstanding  
17 Sections 11346.1 and 11349.6 of the Government Code, the  
18 department shall submit these regulations directly to the Secretary  
19 of State for filing. The regulations shall become effective  
20 immediately upon filing by the Secretary of State. Regulations  
21 shall be subject to public hearing within 120 days of filing with  
22 the Secretary of State and shall comply with Sections 11346.8 and  
23 11346.9 of the Government Code or shall be repealed.

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

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

35 SEC. 3. Section 125001 of the Health and Safety Code is  
36 amended to read:

37 125001. (a) The department shall establish a program for the  
38 development, provision, and evaluation of genetic disease testing,  
39 and may provide laboratory testing facilities or make grants to,  
40 contract with, or make payments to, any laboratory that it deems

1 qualified and ~~cost-effective~~ *cost effective* to conduct testing or with  
2 any metabolic specialty clinic to provide necessary treatment with  
3 qualified specialists. The program shall provide genetic screening  
4 and followup services for persons who have the screening.

5 (b) The department shall expand statewide screening of  
6 newborns to include tandem mass spectrometry screening for fatty  
7 acid oxidation, amino acid, and organic acid disorders and  
8 congenital adrenal hyperplasia as soon as possible. The department  
9 shall provide information with respect to these disorders and  
10 available testing resources to all women receiving prenatal care  
11 and to all women admitted to a hospital for delivery. If the  
12 department is unable to provide this statewide screening by August  
13 1, 2005, the department shall temporarily obtain these testing  
14 services through a competitive bid process from one or more public  
15 or private laboratories that meet the department's requirements  
16 for testing, quality assurance, and reporting. If the department  
17 determines that contracting for these services is more cost effective,  
18 and meets the other requirements of this chapter, than purchasing  
19 the tandem mass spectrometry equipment themselves, the  
20 department shall contract with one or more public or private  
21 laboratories.

22 (c) The department shall expand statewide screening of  
23 newborns to include screening for severe combined  
24 immunodeficiency (SCID) as soon as possible. In implementing  
25 the SCID screening test, the department shall also screen for other  
26 T-cell lymphopenias that are detectable as a result of screening  
27 for SCID, insofar as it does not require additional costs or  
28 equipment beyond that needed to test for SCID.

29 (d) ~~The~~ *Until January 1, 2018, the* department shall expand  
30 statewide screening of newborns to include screening for the  
31 following types of lysosomal storage diseases: ~~Fabry disease;~~  
32 ~~Gaucher disease;~~ Hurler syndrome, also known as  
33 mucopolysaccharidosis type I (MPSI), *and* Krabbe disease;  
34 ~~Niemann-Pick disease, and Pompe disease.~~