

**Introduced by Senator Walters**February 11, 2013

---

---

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 224, as introduced, Walters. 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, 2019, to expand statewide screening of newborns to include screening for 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.

By authorizing moneys in the continuously appropriated GDTF to be used for screening newborns for this additional disease, the 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. This act shall be known, and may be cited, as  
2 Jacquelyn’s Law.

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  
19 this section, subject to all terms and conditions of each enrollee’s  
20 or insured’s health care service plan or insurance coverage,  
21 whichever is applicable, including, but not limited to, copayments  
22 and 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.

26 (2) The department shall expeditiously undertake all steps  
27 necessary to implement the fee collection process, including

1 personnel, contracts, and data processing, so as to initiate the fee  
2 collection process at the earliest opportunity.

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

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

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

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

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

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

39 (c) (1) The Legislature finds that timely implementation of  
40 changes in genetic screening programs and continuous maintenance

1 of quality statewide services requires expeditious regulatory and  
2 administrative procedures to obtain the most cost-effective  
3 electronic data processing, hardware, software services, testing  
4 equipment, and testing and followup services.

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

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

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

1 and implementation of the expansion, and to the maintenance and  
2 operation of the Genetic Disease Branch Screening Information  
3 System, including change requests, once the expansion is  
4 implemented.

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

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

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

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

36 125001. (a) The department shall establish a program for the  
37 development, provision, and evaluation of genetic disease testing,  
38 and may provide laboratory testing facilities or make grants to,  
39 contract with, or make payments to, any laboratory that it deems  
40 qualified and ~~cost-effective~~ *cost effective* to conduct testing or with

1 any metabolic specialty clinic to provide necessary treatment with  
2 qualified specialists. The program shall provide genetic screening  
3 and followup services for persons who have the screening.

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

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

28 (d) *Until January 1, 2019, the department shall expand statewide*  
29 *screening of newborns to include screening for the following types*  
30 *of lysosomal storage diseases: Hurler syndrome, also known as*  
31 *mucopolysaccharidosis type I (MPSI), and Krabbe disease.*