

AMENDED IN SENATE MAY 28, 2013

SENATE BILL

No. 224

Introduced by Senator Walters

February 11, 2013

An act to ~~amend Sections 124977 and 125001~~ *add and repeal Section 125001.5* of the Health and Safety Code, relating to public health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 224, as amended, 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~~ *the* screening of newborns *in Orange County* 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 125001.5 is added to the Health and Safety*
4 *Code, to read:*

5 *125001.5. (a) The department shall establish a pilot program*
6 *to expand in Orange County the screening program established*
7 *in Section 125001 to include the screening of newborns in that*
8 *county for Krabbe disease.*

9 *(b) The expenditure of funds from the Genetic Disease Testing*
10 *Fund shall be authorized for implementation of this section and*
11 *may 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 *(c) This section shall remain in effect only until January 1, 2019,*
19 *and as of that date is repealed, unless a later enacted statute, that*
20 *is enacted before January 1, 2019, deletes or extends that date.*

21 ~~SEC. 2. Section 124977 of the Health and Safety Code is~~
22 ~~amended to read:~~

23 ~~124977. (a) It is the intent of the Legislature that, unless~~
24 ~~otherwise specified, the genetic disease testing program carried~~

1 out pursuant to this chapter be fully supported from fees collected
2 for services provided by the program.

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

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

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

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

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

37 ~~(5) The department shall set guidelines for invoicing, charging,~~
38 ~~and collecting from approved researchers the amount necessary~~
39 ~~to cover all expenses associated with research application requests~~
40 ~~made under this section, data linkage, retrieval, data processing,~~

1 data entry, reinventory, and shipping of blood samples or their
2 components and related data management.

3 ~~(6) The only funds from the Genetic Disease Testing Fund that
4 may be used for the purpose of supporting the pregnancy blood
5 sample storage, testing, and research activities of the Birth Defects
6 Monitoring Program are those prenatal screening fees assessed
7 and collected prior to the creation of the Birth Defects Monitoring
8 Program Fund specifically to support those Birth Defects
9 Monitoring Program activities.~~

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

20 ~~(e) (1) The Legislature finds that timely implementation of
21 changes in genetic screening programs and continuous maintenance
22 of quality statewide services requires expeditious regulatory and
23 administrative procedures to obtain the most cost-effective
24 electronic data processing, hardware, software services, testing
25 equipment, and testing and followup services.~~

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

34 ~~(3) The expenditure of funds from the Genetic Disease Testing
35 Fund for implementation of the tandem mass spectrometry
36 screening for fatty acid oxidation, amino acid, and organic acid
37 disorders, and screening for congenital adrenal hyperplasia may
38 be implemented through the amendment of the Genetic Disease
39 Branch Screening Information System contracts and shall not be
40 subject to Chapter 3 (commencing with Section 12100) of Part 2~~

1 of Division 2 of the Public Contract Code, Article 4 (commencing
2 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title
3 2 of the Government Code, and any policies, procedures,
4 regulations, or manuals authorized by those laws.

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

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

1 the Secretary of State and shall comply with Sections 11346.8 and
2 11346.9 of the Government Code or shall be repealed.

3 (2) ~~The Office of Administrative Law shall provide for the~~
4 ~~printing and publication of these regulations in the California Code~~
5 ~~of Regulations. Notwithstanding Chapter 3.5 (commencing with~~
6 ~~Section 11340) of Part 1 of Division 3 of Title 2 of the Government~~
7 ~~Code, the regulations adopted pursuant to this chapter shall not be~~
8 ~~repealed by the Office of Administrative Law and shall remain in~~
9 ~~effect until revised or repealed by the department.~~

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

14 ~~SEC. 3. Section 125001 of the Health and Safety Code is~~
15 ~~amended to read:~~

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

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

1 ~~(e) The department shall expand statewide screening of~~
2 ~~newborns to include screening for severe combined~~
3 ~~immunodeficiency (SCID) as soon as possible. In implementing~~
4 ~~the SCID screening test, the department shall also screen for other~~
5 ~~T-cell lymphopenias that are detectable as a result of screening~~
6 ~~for SCID, insofar as it does not require additional costs or~~
7 ~~equipment beyond that needed to test for SCID.~~

8 ~~(d) Until January 1, 2019, the department shall expand statewide~~
9 ~~screening of newborns to include screening for the following types~~
10 ~~of lysosomal storage diseases: Hurler syndrome, also known as~~
11 ~~mucopolysaccharidosis type I (MPSI), and Krabbe disease.~~