

Introduced by Senator Strickland

February 14, 2012

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 introduced, 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 to expand statewide screening of newborns to include screening for 6 types of lysosomal storage diseases, 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 Fund consistent with this section,
19 subject to all terms and conditions of each enrollee's or insured's
20 health care service plan or insurance coverage, whichever is
21 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.

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

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

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

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

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

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

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

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

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

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

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

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

(d) (1) The department may adopt emergency regulations to implement and make specific this chapter in accordance with

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

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

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

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

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

(b) The department shall expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and

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

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

22 (d) *The department shall expand statewide screening of*
23 *newborns to include screening for the following types of lysosomal*
24 *storage diseases: Fabry disease, Gaucher disease, Hurler*
25 *syndrome (MPS1), Krabbe disease, Niemann-Pick disease, and*
26 *Pompe disease.*