

AMENDED IN ASSEMBLY MAY 27, 2011
AMENDED IN ASSEMBLY APRIL 7, 2011
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CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 395

Introduced by Assembly Member Pan

February 14, 2011

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

LEGISLATIVE COUNSEL'S DIGEST

AB 395, 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. 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 also authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis and biotinidase 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 require the department to expand statewide screening of newborns to include screening for severe combined

immunodeficiency (SCID) and, *insofar as it does not require additional costs, other T-cell lymphopenias detectable as a result of screening for SCID, and would make related changes.*

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. 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 provision of law, any fees charged for
12 prenatal screening and followup services provided to persons
13 enrolled in the Medi-Cal program, health care service plan
14 enrollees, or persons covered by health insurance policies, shall
15 be paid in full and deposited in the Genetic Disease Testing Fund
16 or the Birth Defects Monitoring Fund consistent with this section,
17 subject to all terms and conditions of each enrollee’s or insured’s
18 health care service plan or insurance coverage, whichever is
19 applicable, including, but not limited to, copayments and
20 deductibles applicable to these services, and only if these
21 copayments, deductibles, or limitations are disclosed to the
22 subscriber or enrollee pursuant to the disclosure provisions of
23 Section 1363.

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

28 (3) Effective for services provided on and after July 1, 2002,
29 the department shall charge a fee to the hospital of birth, or, for
30 births not occurring in a hospital, to families of the newborn, for
31 newborn screening and followup services. The hospital of birth
32 and families of newborns born outside the hospital shall make

1 payment in full to the Genetic Disease Testing Fund. The
2 department shall not charge or bill Medi-Cal beneficiaries for
3 services provided under this chapter.

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

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

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

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

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

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

38 (2) The expenditure of funds from the Genetic Disease Testing
39 Fund for these purposes shall not be subject to Section 12102 of,
40 and Chapter 2 (commencing with Section 10290) of Part 2 of

1 Division 2 of, the Public Contract Code, or to Division 25.2
2 (commencing with Section 38070). The department shall provide
3 the Department of Finance with documentation that equipment
4 and services have been obtained at the lowest cost consistent with
5 technical requirements for a comprehensive high-quality program.

6 (3) The expenditure of funds from the Genetic Disease Testing
7 Fund for implementation of the Tandem Mass Spectrometry
8 screening for fatty acid oxidation, amino acid, and organic acid
9 disorders, and screening for congenital adrenal hyperplasia 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 3 (commencing with Section 12100) of Part 2
13 of Division 2 of the Public Contract Code, Article 4 (commencing
14 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title
15 2 of the Government Code, and any policies, procedures,
16 regulations or manuals authorized by those laws.

17 (4) The expenditure of funds from the Genetic Disease Testing
18 Fund for the expansion of the Genetic Disease Branch Screening
19 Information System to include cystic fibrosis, biotinidase, and
20 severe combined immunodeficiency (SCID) may be implemented
21 through the amendment of the Genetic Disease Branch Screening
22 Information System contracts, and shall not be subject to Chapter
23 2 (commencing with Section 10290) or Chapter 3 (commencing
24 with Section 12100) of Part 2 of Division 2 of the Public Contract
25 Code, Article 4 (commencing with Section 19130) of Chapter 5
26 of Part 2 of Division 5 of Title 2 of the Government Code, or
27 Sections 4800 to 5180, inclusive, of the State Administrative
28 Manual as they relate to approval of information technology
29 projects or approval of increases in the duration or costs of
30 information technology projects. This paragraph shall apply to the
31 design, development, and implementation of the expansion, and
32 to the maintenance and operation of the Genetic Disease Branch
33 Screening Information System, including change requests, once
34 the expansion is implemented.

35 (d) (1) The department may adopt emergency regulations to
36 implement and make specific this chapter in accordance with
37 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division
38 3 of Title 2 of the Government Code. For the purposes of the
39 Administrative Procedure Act, the adoption of regulations shall
40 be deemed an emergency and necessary for the immediate

1 preservation of the public peace, health and safety, or general
2 welfare. Notwithstanding Chapter 3.5 (commencing with Section
3 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
4 these emergency regulations shall not be subject to the review and
5 approval of the Office of Administrative Law. Notwithstanding
6 Sections 11346.1 and 11349.6 of the Government Code, the
7 department shall submit these regulations directly to the Secretary
8 of State for filing. The regulations shall become effective
9 immediately upon filing by the Secretary of State. Regulations
10 shall be subject to public hearing within 120 days of filing with
11 the Secretary of State and shall comply with Sections 11346.8 and
12 11346.9 of the Government Code or shall be repealed.

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

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

24 SEC. 2. Section 125001 of the Health and Safety Code is
25 amended to read:

26 125001. (a) The department shall establish a program for the
27 development, provision, and evaluation of genetic disease testing,
28 and may provide laboratory testing facilities or make grants to,
29 contract with, or make payments to, any laboratory that it deems
30 qualified and cost-effective to conduct testing or with any
31 metabolic specialty clinic to provide necessary treatment with
32 qualified specialists. The program shall provide genetic screening
33 and followup services for persons who have the screening.

34 (b) The department shall expand statewide screening of
35 newborns to include tandem mass spectrometry screening for fatty
36 acid oxidation, amino acid, and organic acid disorders and
37 congenital adrenal hyperplasia as soon as possible. The department
38 shall provide information with respect to these disorders and
39 available testing resources to all women receiving prenatal care
40 and to all women admitted to a hospital for delivery. If the

1 department is unable to provide this statewide screening by August
2 1, 2005, the department shall temporarily obtain these testing
3 services through a competitive bid process from one or more public
4 or private laboratories that meet the department's requirements
5 for testing, quality assurance, and reporting. If the department
6 determines that contracting for these services is more cost-effective,
7 and meets the other requirements of this chapter, than purchasing
8 the tandem mass spectrometry equipment themselves, the
9 department shall contract with one or more public or private
10 laboratories.

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