

AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 395

Introduced by Assembly Member Pan

February 14, 2011

An act to amend ~~Section 125000~~ *Sections 124977 and 125000* of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 395, as amended, Pan. Newborn screening program.

Existing law ~~establishes the Birth Defects Monitoring Program~~ *requires the genetic disease unit* within the State Department of Public Health to detect, as early as possible, preventable heritable or congenital disorders leading to mental retardation or physical defects *promote a statewide program of information, testing, and counseling services to detect specified heritable disorders*. Existing law requires the genetic disease unit to evaluate and prepare recommendations on the implementation of tests for the detection of hereditary and congenital diseases, as specified.

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 add severe combined immuno deficiency (SCID) to the list of diseases for which the genetic disease unit is required to evaluate and prepare recommendations *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 is
2 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

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.

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

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

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

38 (d) (1) The department may adopt emergency regulations to
39 implement and make specific this chapter in accordance with
40 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division

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

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

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

27 ~~SECTION 1.~~

28 *SEC. 2.* Section 125000 of the Health and Safety Code is
29 amended to read:

30 125000. (a) It is the policy of the State of California to make
31 every effort to detect, as early as possible, phenylketonuria and
32 other preventable heritable or congenital disorders leading to
33 mental retardation or physical defects.

34 The department shall establish a genetic disease unit, that shall
35 coordinate all programs of the department in the area of genetic
36 disease. The unit shall promote a statewide program of information,
37 testing, and counseling services and shall have the responsibility
38 of designating tests and regulations to be used in executing this
39 program.

1 The information, tests, and counseling for children shall be in
2 accordance with accepted medical practices and shall be
3 administered to each child born in California once the department
4 has established appropriate regulations and testing methods. The
5 information, tests, and counseling for pregnant women shall be in
6 accordance with accepted medical practices and shall be offered
7 to each pregnant woman in California once the department has
8 established appropriate regulations and testing methods. These
9 regulations shall follow the standards and principles specified in
10 Section 124980. The department may provide laboratory testing
11 facilities or contract with any laboratory that it deems qualified to
12 conduct tests required under this section. However, notwithstanding
13 Section 125005, provision of laboratory testing facilities by the
14 department shall be contingent upon the provision of funding
15 therefor by specific appropriation to the Genetic Disease Testing
16 Fund enacted by the Legislature. If moneys appropriated for
17 purposes of this section are not authorized for expenditure to
18 provide laboratory facilities, the department may nevertheless
19 contract to provide laboratory testing services pursuant to this
20 section and shall perform laboratory services, including, but not
21 limited to, quality control, confirmatory, and emergency testing,
22 necessary to ensure the objectives of this program.

23 (b) The department shall charge a fee for any tests performed
24 pursuant to this section. The amount of the fee shall be established
25 and periodically adjusted by the director in order to meet the costs
26 of this section.

27 (c) The department shall inform all hospitals or physicians and
28 surgeons, or both, of required regulations and tests and may alter
29 or withdraw any of these requirements whenever sound medical
30 practice so indicates. To the extent practicable, the department
31 shall provide notice to hospitals and other payers in advance of
32 any increase in the fees charged for the program.

33 (d) This section shall not apply if a parent or guardian of the
34 newborn child objects to a test on the ground that the test conflicts
35 with his or her religious beliefs or practices.

36 (e) The genetic disease unit is authorized to make grants or
37 contracts or payments to vendors approved by the department for
38 all of the following:

39 (1) Testing and counseling services.

1 (2) Demonstration projects to determine the desirability and
2 feasibility of additional tests or new genetic services.

3 (3) To initiate the development of genetic services in areas of
4 need.

5 (4) To purchase or provide genetic services from any sums as
6 are appropriated for this purpose.

7 (f) The genetic disease unit shall evaluate and prepare
8 recommendations on the implementation of tests for the detection
9 of hereditary and congenital diseases, including, but not limited
10 to, biotinidase deficiency, severe combined immuno deficiency
11 (SCID), and cystic fibrosis. The genetic disease unit shall also
12 evaluate and prepare recommendations on the availability and
13 effectiveness of preventative followup interventions, including the
14 use of specialized medically necessary dietary products.

15 It is the intent of the Legislature that funds for the support of the
16 evaluations and recommendations required pursuant to this
17 subdivision, *including, but not limited to, costs associated with*
18 *the expansion and ongoing administration required to test for*
19 *SCID*, and for the activities authorized pursuant to subdivision (e),
20 shall be provided in the annual Budget Act appropriation from the
21 Genetic Disease Testing Fund.

22 (g) Health care providers that contract with a prepaid group
23 practice health care service plan that annually has at least 20,000
24 births among its membership, may provide, without contracting
25 with the department, any or all of the testing and counseling
26 services required to be provided under this section or the
27 regulations adopted pursuant thereto, if the services meet the
28 quality standards and adhere to the regulations established by the
29 department and the plan pays that portion of a fee established under
30 this section that is directly attributable to the department's cost of
31 administering the testing or counseling service and to any required
32 testing or counseling services provided by the state for plan
33 members. The payment by the plan, as provided in this subdivision,
34 shall be deemed to fulfill any obligation the provider or the
35 provider's patient may have to the department to pay a fee in
36 connection with the testing or counseling service.

37 (h) The department may appoint experts in the area of genetic
38 screening, including, but not limited to, cytogenetics, molecular
39 biology, prenatal, specimen collection, and ultrasound to provide
40 expert advice and opinion on the interpretation and enforcement

1 of regulations adopted pursuant to this section. These experts shall
2 be designated agents of the state with respect to their assignments.
3 These experts shall receive no salary, but shall be reimbursed for
4 expenses associated with the purposes of this section. All expenses
5 of the experts for the purposes of this section shall be paid from
6 the Genetic Disease Testing Fund.

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