

ASSEMBLY BILL

No. 395

Introduced by Assembly Member Pan

February 14, 2011

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

LEGISLATIVE COUNSEL'S DIGEST

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

Existing law establishes the Birth Defects Monitoring Program 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. 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.

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.

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 125000 of the Health and Safety Code
- 2 is amended to read:
- 3 125000. (a) It is the policy of the State of California to make
- 4 every effort to detect, as early as possible, phenylketonuria and

1 other preventable heritable or congenital disorders leading to
2 mental retardation or physical defects.

3 The department shall establish a genetic disease unit, that shall
4 coordinate all programs of the department in the area of genetic
5 disease. The unit shall promote a statewide program of information,
6 testing, and counseling services and shall have the responsibility
7 of designating tests and regulations to be used in executing this
8 program.

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

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

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

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

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

7 (1) Testing and counseling services.

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

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

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

14 (f) The genetic disease unit shall evaluate and prepare
15 recommendations on the implementation of tests for the detection
16 of hereditary and congenital diseases, including, but not limited
17 to, biotinidase deficiency, *severe combined immuno deficiency*
18 (*SCID*), and cystic fibrosis. The genetic disease unit shall also
19 evaluate and prepare recommendations on the availability and
20 effectiveness of preventative followup interventions, including the
21 use of specialized medically necessary dietary products.

22 It is the intent of the Legislature that funds for the support of the
23 evaluations and recommendations required pursuant to this
24 subdivision, and for the activities authorized pursuant to
25 subdivision (e), shall be provided in the annual Budget Act
26 appropriation from the Genetic Disease Testing Fund.

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

1 provider's patient may have to the department to pay a fee in
2 connection with the testing or counseling service.

3 (h) The department may appoint experts in the area of genetic
4 screening, including, but not limited to, cytogenetics, molecular
5 biology, prenatal, specimen collection, and ultrasound to provide
6 expert advice and opinion on the interpretation and enforcement
7 of regulations adopted pursuant to this section. These experts shall
8 be designated agents of the state with respect to their assignments.
9 These experts shall receive no salary, but shall be reimbursed for
10 expenses associated with the purposes of this section. All expenses
11 of the experts for the purposes of this section shall be paid from
12 the Genetic Disease Testing Fund.