

AMENDED IN ASSEMBLY APRIL 21, 2015

AMENDED IN ASSEMBLY MARCH 25, 2015

AMENDED IN ASSEMBLY MARCH 11, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 170

Introduced by Assembly Member Gatto

January 22, 2015

An act to amend Section 125000 of, and to add Sections 125003 and 125004 to, the Health and Safety Code, relating to newborn screening.

LEGISLATIVE COUNSEL'S DIGEST

AB 170, as amended, Gatto. Newborn screening: genetic diseases: blood samples collected.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing, and the program is required to provide genetic screening and followup services for persons who have the screening. The program includes statewide screening of newborn children through the collection of blood samples, unless the parent or guardian objects on the grounds of religious beliefs or practices.

This bill would instead prohibit the department from both testing a newborn child unless the parent or guardian is fully informed, as specified, and from storing, retaining, or using for medical research a blood sample collected unless the parent or guardian provides informed consent, as specified. *provide that the program for testing the blood sample of a newborn child and the authority to store, retain, or use the sample for medical research would not apply to a parent or guardian of the newborn child who objects to the testing program. The bill would*

require the department to provide information about the testing program, and to obtain a form signed by the parent or guardian acknowledging receiving information regarding the storage, retention, and use of the newborn child's blood sample for medical research. The bill would authorize a parent or guardian of a minor child, and the newborn child, once he or she is at least 18 years of age, to request that the department destroy or the blood sample, not use it for research purposes, or both, the blood sample, and the bill would require the department would be required to do so to comply with the request. The bill would also require the department to prepare and provide informational materials, to be distributed as specified, regarding the same information about the newborn child's blood sample collected pursuant to the program that includes, but is not limited to, program, information on storage, retention, and use of the blood sample; for medical research, and the right of specified persons to request that the blood sample be destroyed or not used for research purposes, or both, in a separate, single-page format. The bill would also require the department to prepare and provide a standard informed consent informational acceptance form, to be distributed as specified, that includes, among other things, an explanation of the newborn child screening test and a space for the parent or legal guardian of the newborn child to indicate his or her consent to the storage, retention, and use of the blood sample for medical research: a brief, plain language explanation of, and the purpose for, the newborn child screening test and retention of newborn child blood samples. The bill would require the informational acceptance form to be provided to, and signed by, the parent or guardian when either version of the informational materials is provided. The bill would require specified persons to distribute the informational material and the informational acceptance form, including requiring the local registrar of births to provide a copy of the informational material and a copy of the standard informational acceptance form to each person registering the birth of a newborn that occurred outside of a perinatal licensed health facility, as specified. The bill would also require the local registrar to notify the local health officer and the department of each of these registrations by the local registrar. By imposing additional duties on local registrars of births, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no-yes.

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) (1) It is the policy of the State of California to
4 make every effort to detect, as early as possible, phenylketonuria
5 and other preventable heritable or congenital disorders leading to
6 intellectual disability or physical defects.

7 (2) The department shall establish a genetic disease unit, that
8 shall coordinate all programs of the department in the area of
9 genetic disease. The unit shall promote a statewide program of
10 information, testing, and counseling services and shall have the
11 responsibility of designating tests and regulations to be used in
12 executing this program.

13 (3) The information, tests, and counseling for children shall be
14 in accordance with accepted medical practices and shall be
15 administered to each child born in California. The department shall
16 provide information about the tests and shall obtain the informed
17 consent of a signed informational acknowledgment form for the
18 receipt of information by the parent or guardian of a newborn child
19 for regarding the storage, retention, and use of the newborn child's
20 blood sample for medical research. The department shall establish
21 appropriate regulations and testing methods. The information,
22 tests, and counseling for pregnant women shall be in accordance
23 with accepted medical practices and shall be offered to each
24 pregnant woman in California once the department has established
25 appropriate regulations and testing methods. These regulations
26 shall follow the standards and principles specified in Section
27 124980. The department may provide laboratory testing facilities
28 or contract with any laboratory that it deems qualified to conduct
29 tests required under this section. However, notwithstanding former

1 Section 125005, provision of laboratory testing facilities by the
2 department shall be contingent upon the provision of funding
3 therefor by specific appropriation to the Genetic Disease Testing
4 Fund enacted by the Legislature. If moneys appropriated for
5 purposes of this section are not authorized for expenditure to
6 provide laboratory facilities, the department may nevertheless
7 contract to provide laboratory testing services pursuant to this
8 section and shall perform laboratory services, including, but not
9 limited to, quality control, confirmatory, and emergency testing,
10 necessary to ensure the objectives of this program.

11 (b) The department shall charge a fee for any tests performed
12 pursuant to this section. The amount of the fee shall be established
13 and periodically adjusted by the director in order to meet the
14 *reasonable* costs of this section.

15 (c) The department shall inform all hospitals or physicians and
16 surgeons, or both, of required regulations and tests and may alter
17 or withdraw any of these requirements whenever sound medical
18 practice so indicates. To the extent practicable, the department
19 shall provide notice to hospitals and other payers in advance of an
20 increase in the fees charged for the program.

21 (d) (1) ~~A test shall not be performed on any newborn child~~
22 ~~unless the parent or guardian is fully informed of the purpose and~~
23 ~~benefits of testing for preventable heritable and congenital disorders~~
24 ~~and is given a reasonable opportunity to refuse a newborn child~~
25 ~~screening test on the ground that the test conflicts with his or her~~
26 ~~religious beliefs or practices.~~

27 (2) ~~A newborn child blood sample shall not be stored, retained,~~
28 ~~and used by the department for medical research unless the parent~~
29 ~~or guardian is fully informed of the benefits of research regarding~~
30 ~~preventing heritable and congenital disorders and provides~~
31 ~~informed consent to the storage, retention, and use of the newborn~~
32 ~~child blood sample collected.~~

33 (d) *This section shall not apply to a parent or guardian of a*
34 *newborn child who objects to a test.*

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

38 (1) Testing and counseling services.

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

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

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

5 (f) (1) The genetic disease unit shall evaluate and prepare
6 recommendations on the implementation of tests for the detection
7 of hereditary and congenital diseases, including, but not limited
8 to, biotinidase deficiency and cystic fibrosis. The genetic disease
9 unit shall also evaluate and prepare recommendations on the
10 availability and effectiveness of preventative followup
11 interventions, including the use of specialized medically necessary
12 dietary products.

13 ~~It~~

14 (2) *It* is the intent of the Legislature that funds for the support
15 of the evaluations and recommendations required pursuant to this
16 subdivision, and for the activities authorized pursuant to
17 subdivision (e), shall be provided in the annual Budget Act
18 appropriation from the Genetic Disease Testing Fund.

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

35 (h) The department may appoint experts in the area of genetic
36 screening, including, but not limited to, cytogenetics, molecular
37 biology, prenatal, specimen collection, and ultrasound, to provide
38 expert advice and opinion on the interpretation and enforcement
39 of regulations adopted pursuant to this section. These experts shall
40 be designated agents of the state with respect to their assignments.

1 These experts shall *not receive no* a salary, but shall be reimbursed
2 for expenses associated with the purposes of this section. All
3 expenses of the experts for the purposes of this section shall be
4 paid from the Genetic Disease Testing Fund.

5 (i) A parent or legal guardian of a minor may request the
6 department ~~to~~ destroy *the blood sample of the minor collected as*
7 *a newborn*, or not use *it* for research purposes, or both, ~~the blood~~
8 ~~sample of the minor collected as a newborn~~, and the department
9 shall ~~do so~~ comply with that request.

10 (j) An individual who is at least 18 years of age may request
11 the department ~~to~~ destroy *his or her blood sample that was*
12 *collected as a newborn*, or not use *it* for research purposes, or both,
13 ~~his or her blood sample that was collected~~, and the department
14 shall ~~do so~~ comply with that request.

15 SEC. 2. Section 125003 is added to the Health and Safety Code,
16 to read:

17 125003. (a) The department shall prepare and provide
18 informational materials regarding newborn child blood samples
19 collected pursuant to this article that include, but are not limited
20 to, all of the following:

21 (1) Storage, retention, and use of the blood sample.

22 (2) The parent or legal guardian's right to request that his or her
23 minor child's blood sample be destroyed or not used for research
24 purposes, or both, and the information necessary to make that
25 request.

26 (3) The right of an individual who is at least 18 years of age to
27 request that his or her blood sample be destroyed or not used for
28 research purposes, or both, and the information necessary to make
29 that request.

30 (b) *These informational materials shall be confined to a single*
31 *page and presented in a separate document from informational*
32 *materials pertaining to the newborn screening program.*

33 (b)

34 (c) The department shall provide to a parent or legal guardian
35 the standard ~~informed consent informational acceptance~~ form
36 provided in Section 125004 regarding the options for newborn
37 child screening and retention of newborn child blood samples
38 collected pursuant to this article.

39 (e)

1 (d) The informational materials and the standard-informed
2 ~~consent~~ *informational acceptance* form prepared and provided by
3 the department shall be distributed as follows:

4 (1) Every birth attendant engaged in providing perinatal care
5 shall provide a pregnant woman, prior to the estimated date of
6 delivery, with a copy of the informational materials and a copy of
7 the standard-informed ~~consent~~ *informational acceptance* form
8 provided by the department.

9 (2) Every perinatal licensed health facility shall provide each
10 pregnant woman admitted for delivery with a copy of the
11 informational materials and a copy of the standard-informed
12 ~~consent~~ *informational acceptance* form provided by the department,
13 prior to collection of the blood sample, if that information or
14 standard-informed ~~consent~~ *informational acceptance* form has not
15 been provided pursuant to paragraph (1).

16 (3) The local registrar of births shall provide a copy of the
17 informational material and a copy of the standard ~~informed consent~~
18 *informational acceptance* form provided by the department to each
19 person registering the birth of a newborn that occurred outside of
20 a perinatal licensed health facility when the newborn was not
21 admitted to a perinatal licensed health facility within the first 30
22 days of age. The local health officer and the department shall be
23 notified of each of these registrations by the local registrar.

24 (d) For the purposes of this section, the following terms shall
25 have the following meanings:

26 (1) “Birth attendant” means a person licensed or certified by
27 the state to provide maternity care and to deliver pregnant women
28 or to practice medicine.

29 (2) “Perinatal licensed health facility” means a health facility
30 licensed by the state and approved to provide perinatal, delivery,
31 newborn intensive care, newborn nursery, or pediatric services.

32 SEC. 3. Section 125004 is added to the Health and Safety Code,
33 to read:

34 125004. (a) The department shall prepare a standard ~~informed~~
35 ~~consent~~ *informational acceptance* form that includes all of the
36 following:

37 (1) A brief, plain language explanation of, and the purpose for,
38 the newborn child screening test and retention of newborn child
39 blood samples collected pursuant to this article.

1 (2) A description of the benefits of both early newborn child
2 screening and the associated research undertaken regarding
3 preventable heritable or congenital disorders.

4 (3) *A description of the California Biobank Program,*
5 *specifically as it pertains to the Genetic Disease Screening*
6 *Program, and subsequent storage, retention, and use of the*
7 *newborn child's blood sample for medical research.*

8 (3)

9 (4) A space for the parent or legal guardian of the newborn child
10 to acknowledge receipt of informational materials regarding the
11 newborn child screening test, *and the storage, retention, and use*
of the newborn child's blood sample for medical research.

12 (4) ~~A space for the parent or legal guardian of the newborn child
to indicate his or her consent to the storage, retention, and use of
the blood sample for medical research.~~

13 (5) ~~A space for the parent or legal guardian of the newborn child
to indicate his or her request for information about the right to
refuse a newborn child screening test on the ground that the test
conflicts with his or her religious beliefs or practices.~~

14 (6)

15 (a) A space for the parent or legal guardian of the newborn
16 child to sign and date the form.

17 (b) ~~The department shall not store, retain, or use for medical
research a newborn child's blood sample collected and used for
the newborn screening test unless the parent or guardian of the
newborn child has first indicated his or her consent on the
completed standard informed consent form.~~

18 (c)

19 (b) A copy of the standard informed consent informational
20 acceptance form shall be maintained with the newborn child's
21 medical records.

22 (d)

23 (c) As used in this article, "informed consent" "informational
24 acceptance form" means a written authorization acknowledgment
25 of received informational materials, signed and dated by a parent
26 or legal guardian of a newborn child.

27 SEC. 4. *If the Commission on State Mandates determines that*
28 *this act contains costs mandated by the state, reimbursement to*
29 *local agencies and school districts for those costs shall be made*

1 *pursuant to Part 7 (commencing with Section 17500) of Division*
2 *4 of Title 2 of the Government Code.*

O