

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 ~~has given fully~~ *provides* informed consent, as specified. 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 not use for research purposes, or both, the blood sample, and the department would be required to do so. The bill would also require the

department to prepare and provide informational materials, to be distributed as specified, regarding the newborn child blood sample collected pursuant to the program that includes, but is not limited to, information on storage, retention, and use of the blood sample, and the right of specified persons to request that the blood sample be destroyed or not used for research purposes, or both. The bill would require the department to prepare and provide a standard informed consent form, to be distributed as specified, ~~that sets forth clearly and in detail specified information.~~ *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.*

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) (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 ~~The~~
8 (2) *The* department shall establish a genetic disease unit, that
9 shall coordinate all programs of the department in the area of
10 genetic disease. The unit shall promote a statewide program of
11 information, testing, and counseling services and shall have the
12 responsibility of designating tests and regulations to be used in
13 executing this program.
14 ~~The~~
15 (3) *The* information, tests, and counseling for children shall be
16 in accordance with accepted medical practices and shall be
17 administered to each child born in ~~California~~ *if the fully California.*
18 *The department shall provide information about the tests and shall*
19 *obtain the* informed consent of the parent or guardian of a newborn
20 ~~child is obtained and once the department has established for the~~
21 *storage, retention, and use of the newborn child's blood sample*
22 *for medical research. The department shall establish* appropriate
23 regulations and testing methods. The information, tests, and

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

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

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

29 (d) (1) A test shall not be performed on any newborn child
30 unless the parent or guardian is fully informed of the purpose and
31 benefits of testing for preventable heritable and congenital disorders
32 and is given a reasonable opportunity to refuse a newborn child
33 screening test on the ground that the test conflicts with his or her
34 religious beliefs or practices.

35 (2) A newborn child blood sample shall not be stored, retained,
36 and used by the department *for medical research* unless the parent
37 or guardian is fully informed of the benefits of research regarding
38 preventing heritable and congenital disorders and ~~is given a~~
39 ~~reasonable opportunity to object~~ *provides informed consent* to the

1 storage, retention, and use of the newborn child blood sample
2 collected.

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

6 (1) Testing and counseling services.

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

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

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

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

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

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

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

11 (i) A parent or legal guardian of a minor may request the
12 department to destroy or not use for research purposes, or both,
13 the blood sample of the minor collected as a newborn, and the
14 department shall do so.

15 (j) An individual who is at least 18 years of age may request
16 the department to destroy or not use for research purposes, or both,
17 his or her blood sample that was collected, and the department
18 shall do so.

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

21 125003. (a) The department shall prepare and provide
22 informational materials regarding newborn child blood samples
23 collected pursuant to this article that include, but are not limited
24 to, all of the following:

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

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

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

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

38 (c) The informational materials and the standard informed
39 consent form prepared and provided by the department shall be
40 distributed as follows:

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

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

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

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

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

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

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

125004. (a) The department shall prepare a standard informed consent form ~~setting forth clearly and in detail~~ *that includes* all of the following:

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

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

(3) ~~That~~ *A space for* the parent or legal guardian of the newborn child ~~may consent to~~ *acknowledge receipt of informational materials regarding* the newborn child screening test.

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

4 ~~(4)~~

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

9 ~~(5) That if the parent or legal guardian of the newborn child~~
10 ~~refuses to have the newborn child screening test done, he or she~~
11 ~~accepts all responsibility and liability for the possible~~
12 ~~consequences.~~

13 ~~(6) A description of the health risks associated with foregoing~~
14 ~~the newborn child screening test.~~

15 ~~(7) That the parent or legal guardian of the newborn child may~~
16 ~~consent to the storage, retention, and use of the blood sample.~~

17 ~~(8) That the parent or legal guardian of the newborn child may~~
18 ~~request the department to destroy or not use for research purposes,~~
19 ~~or both, the blood sample collected and screened.~~

20 (6) *A space for the parent or legal guardian of the newborn*
21 *child to sign and date the form.*

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

27 ~~(b)~~

28 (c) *A copy of the standard informed consent form shall be*
29 *maintained with the newborn child's medical records.*

30 (d) *As used in this article, "informed consent" means a written*
31 *authorization signed and dated by a parent or legal guardian of*
32 *a newborn child.*