

# AS PROPOSED TO BE AMENDED

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 and storing, retaining, or using a blood sample collected unless the parent or guardian has given fully informed consent, as specified. The bill 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.

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  
5 other preventable heritable or congenital disorders leading to  
6 intellectual disability or physical defects.  
7 The department shall establish a genetic disease unit, that shall  
8 coordinate all programs of the department in the area of genetic  
9 disease. The unit shall promote a statewide program of information,  
10 testing, and counseling services and shall have the responsibility  
11 of designating tests and regulations to be used in executing this  
12 program.  
13 The information, tests, and counseling for children shall be in  
14 accordance with accepted medical practices and shall be  
15 administered to each child born in California. *The Department shall provide*  
16 *information about the test and shall obtain the* ~~if the fully-informed~~  
17 ~~and once the~~ *for the storage, retention, and use of the newborn child's blood*  
18 *sample for medical research.* ~~The~~ department ~~has~~ shall established appropriate regulations  
19 and testing methods. The information, tests, and counseling for  
20 pregnant women shall be in accordance with accepted medical  
21 practices and shall be offered to each pregnant woman in California  
22 once the department has established appropriate regulations and  
23 testing methods. These regulations shall follow the standards and  
24 principles specified in Section 124980. The department may  
25 provide laboratory testing facilities or contract with any laboratory  
26 that it deems qualified to conduct tests required under this section.  
27 However, notwithstanding former Section 125005, provision of  
28 laboratory testing facilities by the department shall be contingent  
upon the provision of funding therefor by specific appropriation

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

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

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

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

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

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

37 (1) Testing and counseling services.

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

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

33 (h) The department may appoint experts in the area of genetic  
34 screening, including, but not limited to, cytogenetics, molecular  
35 biology, prenatal, specimen collection, and ultrasound to provide  
36 expert advice and opinion on the interpretation and enforcement  
37 of regulations adopted pursuant to this section. These experts shall  
38 be designated agents of the state with respect to their assignments.  
39 These experts shall receive no salary, but shall be reimbursed for  
40 expenses associated with the purposes of this section. All expenses

1 of the experts for the purposes of this section shall be paid from  
2 the Genetic Disease Testing Fund.

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

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

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

13 125003. (a) The department shall prepare and provide  
14 informational materials regarding newborn child blood samples  
15 collected pursuant to this article that include, but are not limited  
16 to, all of the following:

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

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

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

26 (b) The department shall provide to a parent or legal guardian  
27 the standard informed consent form provided in Section 125004  
28 regarding the options for newborn child screening and retention  
29 of newborn child blood samples collected pursuant to this article.  
30

31 (c) The informational materials and the standard informed  
32 consent form prepared and provided by the department shall be  
33 distributed as follows:

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

38 (2) Every perinatal licensed health facility shall provide each  
39 pregnant woman admitted for delivery with a copy of the  
40 informational materials and a copy of the standard informed

1 consent form provided by the department, prior to collection of  
2 the blood sample, if that information or standard informed consent  
3 form has not been provided pursuant to paragraph (1).

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

12 (e)

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

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

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

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

23 125004. (a) As used in this article "informed consent" means

a written authorization signed and dated by a parent or legal guardian  
of a newborn child. The department shall prepare a standard informed consent form  
setting forth clearly and in detail all of the following:

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

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

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

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

(5) A space for the parent or legal guardian to indicate his or her request for information  
about ~~That the parent or legal guardian of the newborn child has~~

34 the right to refuse a newborn child screening test on the ground  
35 that the test conflicts with his or her religious beliefs or practices.

(6) A space for the parent or legal guardian to sign and date the form.

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

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

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

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

8 (b) **The department may not store, retain, or use for medical research**  
9 **a newborn child's blood sample collected and used for the newborn screening test,**  
10 **unless the parent or guardian of the newborn child indicates his or her consent**  
11 **on a completed informed consent form.**

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