

AMENDED IN ASSEMBLY APRIL 9, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1731

Introduced by Assembly Member Block

February 16, 2012

An act to ~~amend Sections 124977 and 125001 of~~ *add Article 6.6 (commencing with Section 124121) to Chapter 3 of Part 2 of Division 106 of the Health and Safety Code, relating to public health.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1731, as amended, Block. Newborn screening ~~program. program:~~ *critical congenital heart disease.*

Existing law provides for the Newborn and Infant Hearing Screening, Tracking, and Intervention program, under which general acute care hospitals with licensed perinatal services, as specified, are required to administer to newborns a hearing screening test for the identification of hearing loss, as prescribed, using protocols developed by the State Department of Health Care Services, or its designee.

This bill would require general acute care hospitals with licensed perinatal services to offer to parents of a newborn, prior to discharge, a pulse oximetry test for the identification of critical congenital heart disease (CCHD), using protocols approved by the department or its designee. This bill would require the department to phase in implementation of a comprehensive CCHD screening program on or after July 1, 2013, and require 100% participation by these hospitals by December 31, 2016. This bill would require these hospitals to develop a CCHD screening program, as prescribed.

~~Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of~~

~~genetic disease testing. Existing law establishes the continuously appropriated Genetic Disease Testing Fund (GDTF), consisting of fees paid for newborn screening and other 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 authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System, as specified, to include cystic fibrosis, biotinidase, and severe combined immunodeficiency. Existing law exempts the expansion of contracts for this purpose from provisions of the Public Contract Code that establish standards for contracts and requires the Department of General Services to approve these contracts. Existing law also exempts the expansion of contracts for this purpose from standards for personal services contracts and from provisions that give the California Technology Agency authority over the application of information technology for state agencies.~~

~~This bill would require the department to expand statewide screening of newborns as soon as possible to include pulse oximetry screening for critical congenital heart disease, and would exempt the expansion of contracts for this purpose from provisions that establish standards for contracts, require the Department of General Services to approve contracts, and give the California Technology Agency authority over information technology projects, as described above.~~

~~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. Article 6.6 (commencing with Section 124121) is
2 added to Chapter 3 of Part 2 of Division 106 of the Health and
3 Safety Code, to read:

4
5 Article 6.6. Newborn Critical Congenital Heart Disease
6 Screening Program
7

8 124121. The Legislature finds and declares the following:
9 (a) Congenital heart disease affects about seven to nine of every
10 1,000 live births in the United States and is the most common cause
11 of death in the first year of life, with defects accounting for 3

1 *percent of all infant deaths and more than 40 percent of all deaths*
2 *due to congenital malformations.*

3 *(b) Critical congenital heart disease (CCHD) is a group of*
4 *defects that cause severe and life-threatening symptoms and require*
5 *intervention within the first days or first year of life.*

6 *(c) Current methods for detecting CCHD generally include*
7 *prenatal ultrasound screening and careful and repeated clinical*
8 *examinations.*

9 *(d) CCHD is often missed during the routine clinical exam that*
10 *generally is scheduled prior to a newborn's discharge, and many*
11 *cases of CCHD are also missed during discharge and*
12 *postdischarge clinical exams.*

13 *(e) Fetal ultrasound screening programs improve detection of*
14 *major congenital heart defects; however, prenatal diagnosis alone*
15 *picks up less than half of all cases.*

16 *(f) Pulse oximetry is a noninvasive test that estimates the*
17 *percentage of hemoglobin in blood that is saturated with oxygen.*

18 *(g) Virtually all hospitals, including small hospitals, frequently*
19 *use pulse oximetry as a standard of care in their newborn*
20 *nurseries.*

21 *(h) Many newborn lives could potentially be saved by earlier*
22 *detection and treatment of CCHD if hospitals were required to*
23 *perform this simple, noninvasive newborn screening method.*

24 *124122. For purposes of this article, "CCHD" means critical*
25 *congenital heart disease.*

26 *124123. (a) (1) A general acute care hospital with licensed*
27 *perinatal services shall offer to parents of a newborn, prior to*
28 *discharge, a pulse oximetry test for the identification of CCHD,*
29 *using protocols approved by the State Department of Health Care*
30 *Services or its designee. The department shall begin phasing in*
31 *implementation of a comprehensive CCHD screening program by*
32 *general acute care hospitals with licensed perinatal services on*
33 *or after July 1, 2013, and a 100-percent participation rate shall*
34 *be achieved by 2016.*

35 *(2) A hospital described in paragraph (1) shall be responsible*
36 *for developing a screening program that provides competent*
37 *CCHD screening, utilizes appropriate staff and equipment for*
38 *administering the testing, completes the testing prior to the*
39 *newborn's discharge from a newborn nursery unit, refers infants*
40 *with abnormal screening results for appropriate care, maintains*

1 and reports data as required by the department, and provides
2 physician and family-parent education.

3 (b) A pulse oximetry test provided for pursuant to subdivision
4 (a) shall be performed by a licensed physician, licensed registered
5 nurse, or an appropriately trained individual who is supervised
6 in the performance of the test by a licensed health care
7 professional.

8 (c) This section shall not apply to a newborn whose parent or
9 guardian objects to the test on the grounds that the test is in
10 violation of his or her beliefs.

11 SECTION 1. The Legislature finds and declares the following:

12 (a) ~~Congenital heart disease affects about seven to nine of every,~~
13 ~~1000 live births in the United States and is the most common cause~~
14 ~~of death in the first year of life, with defects accounting for 3~~
15 ~~percent of all infant deaths and more than 40 percent of all deaths~~
16 ~~due to congenital malformations.~~

17 (b) ~~Critical congenital heart disease (CCHD) is a group of~~
18 ~~defects that cause severe and life-threatening symptoms and require~~
19 ~~intervention within the first days or first year of life.~~

20 (c) ~~Current methods for detecting CCHD generally include~~
21 ~~prenatal ultrasound screening, and careful and repeated clinical~~
22 ~~examinations.~~

23 (d) ~~CCHD is often missed during the routine clinical exam that~~
24 ~~generally is scheduled prior to a newborn's discharge, and many~~
25 ~~cases of CCHD are also missed during discharge and postdischarge~~
26 ~~clinical exams.~~

27 (e) ~~Fetal ultrasound screening programs improve detection of~~
28 ~~major congenital heart defects; however, prenatal diagnosis alone~~
29 ~~picks up less than half of all cases.~~

30 (f) ~~Pulse oximetry is a noninvasive test that estimates the~~
31 ~~percentage of hemoglobin in blood that is saturated with oxygen.~~

32 (g) ~~Virtually all hospitals, including small hospitals, frequently~~
33 ~~use pulse oximetry as a standard of care in their newborn nurseries.~~

34 (h) ~~Many newborn lives could potentially be saved by earlier~~
35 ~~detection and treatment of CCHD if hospitals were required to~~
36 ~~perform this simple, noninvasive newborn screening method.~~

37 SEC. 2. ~~Section 124977 of the Health and Safety Code is~~
38 ~~amended to read:~~

39 ~~124977. (a) It is the intent of the Legislature that, unless~~
40 ~~otherwise specified, the genetic disease testing program carried~~

1 out pursuant to this chapter be fully supported from fees collected
2 for services provided by the program.

3 (b) (1) The department shall charge a fee to all payers for any
4 tests or activities performed pursuant to this chapter. The amount
5 of the fee shall be established by regulation and periodically
6 adjusted by the director in order to meet the costs of this chapter.
7 Notwithstanding any other provision of law, any fees charged for
8 prenatal screening and followup services provided to persons
9 enrolled in the Medi-Cal program, health care service plan
10 enrollees, or persons covered by health insurance policies, shall
11 be paid in full and deposited in the Genetic Disease Testing Fund
12 or the Birth Defects Monitoring Fund consistent with this section,
13 subject to all terms and conditions of each enrollee's or insured's
14 health care service plan or insurance coverage, whichever is
15 applicable, including, but not limited to, copayments and
16 deductibles applicable to these services, and only if these
17 copayments, deductibles, or limitations are disclosed to the
18 subscriber or enrollee pursuant to the disclosure provisions of
19 Section 1363.

20 (2) The department shall expeditiously undertake all steps
21 necessary to implement the fee collection process, including
22 personnel, contracts, and data processing, so as to initiate the fee
23 collection process at the earliest opportunity.

24 (3) Effective for services provided on and after July 1, 2002,
25 the department shall charge a fee to the hospital of birth, or, for
26 births not occurring in a hospital, to families of the newborn, for
27 newborn screening and followup services. The hospital of birth
28 and families of newborns born outside the hospital shall make
29 payment in full to the Genetic Disease Testing Fund. The
30 department shall not charge or bill Medi-Cal beneficiaries for
31 services provided under this chapter.

32 (4) (A) The department shall charge a fee for prenatal screening
33 to support the pregnancy blood sample storage, testing, and
34 research activities of the Birth Defects Monitoring Program.

35 (B) The prenatal screening fee for activities of the Birth Defects
36 Monitoring Program shall be ten dollars (\$10).

37 (5) The department shall set guidelines for invoicing, charging,
38 and collecting from approved researchers the amount necessary
39 to cover all expenses associated with research application requests
40 made under this section, data linkage, retrieval, data processing,

1 data entry, reinventory, and shipping of blood samples or their
2 components and related data management.

3 ~~(6) The only funds from the Genetic Disease Testing Fund that~~
4 ~~may be used for the purpose of supporting the pregnancy blood~~
5 ~~sample storage, testing, and research activities of the Birth Defects~~
6 ~~Monitoring Program are those prenatal screening fees assessed~~
7 ~~and collected prior to the creation of the Birth Defects Monitoring~~
8 ~~Program Fund specifically to support those Birth Defects~~
9 ~~Monitoring Program activities.~~

10 ~~(7) The Birth Defects Monitoring Program Fund is hereby~~
11 ~~created as a special fund in the State Treasury. Fee revenues that~~
12 ~~are collected pursuant to paragraph (4) shall be deposited into the~~
13 ~~fund and shall be available upon appropriation by the Legislature~~
14 ~~to support the pregnancy blood sample storage, testing, and~~
15 ~~research activities of the Birth Defects Monitoring Program.~~
16 ~~Notwithstanding Section 16305.7 of the Government Code, interest~~
17 ~~earned on funds in the Birth Defects Monitoring Program Fund~~
18 ~~shall be deposited as revenue into the fund to support the Birth~~
19 ~~Defects Monitoring Program.~~

20 ~~(c) (1) The Legislature finds that timely implementation of~~
21 ~~changes in genetic screening programs and continuous maintenance~~
22 ~~of quality statewide services requires expeditious regulatory and~~
23 ~~administrative procedures to obtain the most cost-effective~~
24 ~~electronic data processing, hardware, software services, testing~~
25 ~~equipment, and testing and followup services.~~

26 ~~(2) The expenditure of funds from the Genetic Disease Testing~~
27 ~~Fund for these purposes shall not be subject to Section 12102 of,~~
28 ~~and Chapter 2 (commencing with Section 10290) of Part 2 of~~
29 ~~Division 2 of, the Public Contract Code, or to Division 25.2~~
30 ~~(commencing with Section 38070). The department shall provide~~
31 ~~the Department of Finance with documentation that equipment~~
32 ~~and services have been obtained at the lowest cost consistent with~~
33 ~~technical requirements for a comprehensive high-quality program.~~

34 ~~(3) The expenditure of funds from the Genetic Disease Testing~~
35 ~~Fund for implementation of the Tandem Mass Spectrometry~~
36 ~~screening for fatty acid oxidation, amino acid, and organic acid~~
37 ~~disorders, and screening for congenital adrenal hyperplasia may~~
38 ~~be implemented through the amendment of the Genetic Disease~~
39 ~~Branch Screening Information System contracts and shall not be~~
40 ~~subject to Chapter 3 (commencing with Section 12100) of Part 2~~

1 of Division 2 of the Public Contract Code, Article 4 (commencing
2 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title
3 2 of the Government Code, and any policies, procedures,
4 regulations or manuals authorized by those laws.

5 (4) ~~The expenditure of funds from the Genetic Disease Testing~~
6 ~~Fund for the expansion of the Genetic Disease Branch Screening~~
7 ~~Information System to include cystic fibrosis, biotinidase, severe~~
8 ~~combined immunodeficiency (SCID), and critical congenital heart~~
9 ~~disease may be implemented through the amendment of the Genetic~~
10 ~~Disease Branch Screening Information System contracts, and shall~~
11 ~~not be subject to Chapter 2 (commencing with Section 10290) or~~
12 ~~Chapter 3 (commencing with Section 12100) of Part 2 of Division~~
13 ~~2 of the Public Contract Code, Article 4 (commencing with Section~~
14 ~~19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the~~
15 ~~Government Code, or Sections 4800 to 5180, inclusive, of the~~
16 ~~State Administrative Manual as they relate to approval of~~
17 ~~information technology projects or approval of increases in the~~
18 ~~duration or costs of information technology projects. This~~
19 ~~paragraph shall apply to the design, development, and~~
20 ~~implementation of the expansion, and to the maintenance and~~
21 ~~operation of the Genetic Disease Branch Screening Information~~
22 ~~System, including change requests, once the expansion is~~
23 ~~implemented.~~

24 (d) ~~(1) The department may adopt emergency regulations to~~
25 ~~implement and make specific this chapter in accordance with~~
26 ~~Chapter 3.5 (commencing with Section 11340) of Part 1 of Division~~
27 ~~3 of Title 2 of the Government Code. For the purposes of the~~
28 ~~Administrative Procedure Act, the adoption of regulations shall~~
29 ~~be deemed an emergency and necessary for the immediate~~
30 ~~preservation of the public peace, health and safety, or general~~
31 ~~welfare. Notwithstanding Chapter 3.5 (commencing with Section~~
32 ~~11340) of Part 1 of Division 3 of Title 2 of the Government Code,~~
33 ~~these emergency regulations shall not be subject to the review and~~
34 ~~approval of the Office of Administrative Law. Notwithstanding~~
35 ~~Sections 11346.1 and 11349.6 of the Government Code, the~~
36 ~~department shall submit these regulations directly to the Secretary~~
37 ~~of State for filing. The regulations shall become effective~~
38 ~~immediately upon filing by the Secretary of State. Regulations~~
39 ~~shall be subject to public hearing within 120 days of filing with~~

1 the Secretary of State and shall comply with Sections 11346.8 and
2 11346.9 of the Government Code or shall be repealed.

3 (2) ~~The Office of Administrative Law shall provide for the~~
4 ~~printing and publication of these regulations in the California Code~~
5 ~~of Regulations. Notwithstanding Chapter 3.5 (commencing with~~
6 ~~Section 11340) of Part 1 of Division 3 of Title 2 of the Government~~
7 ~~Code, the regulations adopted pursuant to this chapter shall not be~~
8 ~~repealed by the Office of Administrative Law and shall remain in~~
9 ~~effect until revised or repealed by the department.~~

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

14 ~~SEC. 3. Section 125001 of the Health and Safety Code is~~
15 ~~amended to read:~~

16 ~~125001. (a) The department shall establish a program for the~~
17 ~~development, provision, and evaluation of genetic disease testing,~~
18 ~~and may provide laboratory testing facilities or make grants to,~~
19 ~~contract with, or make payments to, any laboratory that it deems~~
20 ~~qualified and cost-effective to conduct testing or with any~~
21 ~~metabolic specialty clinic to provide necessary treatment with~~
22 ~~qualified specialists. The program shall provide genetic screening~~
23 ~~and followup services for persons who have the screening.~~

24 ~~(b) The department shall expand statewide screening of~~
25 ~~newborns to include tandem mass spectrometry screening for fatty~~
26 ~~acid oxidation, amino acid, and organic acid disorders and~~
27 ~~congenital adrenal hyperplasia as soon as possible. The department~~
28 ~~shall provide information with respect to these disorders and~~
29 ~~available testing resources to all women receiving prenatal care~~
30 ~~and to all women admitted to a hospital for delivery. If the~~
31 ~~department is unable to provide this statewide screening by August~~
32 ~~1, 2005, the department shall temporarily obtain these testing~~
33 ~~services through a competitive bid process from one or more public~~
34 ~~or private laboratories that meet the department's requirements~~
35 ~~for testing, quality assurance, and reporting. If the department~~
36 ~~determines that contracting for these services is more cost-effective,~~
37 ~~and meets the other requirements of this chapter, than purchasing~~
38 ~~the tandem mass spectrometry equipment themselves, the~~
39 ~~department shall contract with one or more public or private~~
40 ~~laboratories.~~

1 ~~(e) The department shall expand statewide screening of~~
2 ~~newborns to include screening for severe combined~~
3 ~~immunodeficiency (SCID) as soon as possible. In implementing~~
4 ~~the SCID screening test, the department shall also screen for other~~
5 ~~T-cell lymphopenias that are detectable as a result of screening~~
6 ~~for SCID, insofar as it does not require additional costs or~~
7 ~~equipment beyond that needed to test for SCID.~~

8 ~~(d) The department shall expand statewide screening of~~
9 ~~newborns as soon as possible to include pulse oximetry screening,~~
10 ~~when feasible between 24 and 48 hours after birth, for critical~~
11 ~~congenital heart disease.~~