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H.B. No. 1672

A BILL TO BE ENTITLED

AN ACT

relating to newborn screening.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 33, Health and Safety Code, is amended by adding Section 33.0021 to read as follows:

Sec. 33.0021. SICKLE-CELL TRAIT. Notwithstanding any provision of this chapter, the department shall include sickle-cell trait in the detection and treatment program established under this chapter, in the screening for heritable diseases conducted under Subchapter B, and the newborn screening services provided under Subchapter C.

SECTION 2. Subchapter B, Chapter 33, Health and Safety Code, is amended by adding Sections 33.0111 and 33.0112 to read as follows:

Sec. 33.0111. DISCLOSURE. (a) The department shall develop a disclosure statement that clearly discloses to the parent, managing conservator, or guardian of a newborn child subjected to screening tests under Section 33.011:

(1) that the department or a laboratory established or approved by the department under Section 33.016 may retain for use by the department or laboratory genetic material used to conduct the newborn screening tests and discloses how the material is managed; and

(2) that the parent, managing conservator, or

1 guardian may limit the use of the genetic material by providing to
2 the department in accordance with Section 33.0112 a written
3 statement prohibiting the department or laboratory from retaining
4 the genetic material.

5 (b) The disclosure statement required by Subsection (a)
6 must be included on the form developed by the department to inform
7 parents about newborn screening. The disclosure statement must:

8 (1) be on a separate sheet of the form;

9 (2) be presented together with the written statement
10 described by Subsection (a)(2) in a format that allows a parent,
11 managing conservator, or guardian of a newborn child to either:

12 (A) sign, detach, and mail a portion of the form
13 to the department to require the department or laboratory to
14 destroy the genetic material on completion of the newborn screening
15 tests; or

16 (B) check a box and sign next to the box on the
17 form a statement indicating the parent, managing conservator, or
18 guardian is requiring the department or laboratory to destroy the
19 genetic material on completion of the newborn screening tests;

20 (3) include instructions on how to complete the
21 portions of the form described by Subdivisions (2)(A) and (B);

22 (4) include the department's mailing address; and

23 (5) be made available to a parent, managing
24 conservator, or guardian of a newborn child through alternative
25 sources.

26 (c) At the time a newborn child is subjected to screening
27 tests under Section 33.011, the physician attending a newborn child

1 or the person attending the delivery of a newborn child that is not
2 attended by a physician shall provide the parent, managing
3 conservator, or guardian of a newborn child a copy of the written
4 disclosure statement developed by the department under this
5 section.

6 (d) The department shall establish procedures for a
7 physician attending a newborn child or the person attending the
8 delivery of a newborn child to provide verification to the
9 department that the physician or person has provided the parent,
10 managing conservator, or guardian of the newborn child the
11 disclosure required under this section.

12 Sec. 33.0112. STATEMENT PROHIBITING RETENTION OF GENETIC
13 MATERIAL. (a) A parent, managing conservator, or guardian of a
14 newborn child may file with the department a signed written
15 statement prohibiting the department or a laboratory established or
16 approved by the department from retaining any genetic material
17 related to the newborn screening tests conducted under this
18 subchapter. A parent, managing conservator, or guardian may file
19 the written statement on a form provided by the department.

20 (b) Not later than the 60th day after the department
21 receives the written statement, the department or laboratory shall
22 destroy the genetic material used in the screening tests.

23 (c) An adult individual may file with the department a
24 written statement instructing the department or a laboratory
25 established or approved by the department to destroy any genetic
26 material of the individual that is retained under this subchapter.

27 SECTION 3. Subchapter B, Chapter 33, Health and Safety

1 Code, is amended by adding Section 33.017 to read as follows:

2 Sec. 33.017. CONFIDENTIALITY. (a) Reports, records, and
3 information obtained or developed by the department under this
4 chapter are confidential and are not subject to disclosure under
5 Chapter 552, Government Code, are not subject to subpoena, and may
6 not otherwise be released or made public except as provided by this
7 section.

8 (b) Notwithstanding other law, reports, records, and
9 information obtained or developed by the department under this
10 chapter may be disclosed:

11 (1) for purposes of diagnosis or follow-up authorized
12 under Section 33.014;

13 (2) with the consent of each identified individual or
14 an individual authorized to consent on behalf of an identified
15 child;

16 (3) as authorized by court order;

17 (4) to a medical examiner authorized to conduct an
18 autopsy on a child or an inquest on the death of a child; or

19 (5) to public health programs of the department for
20 public health research purposes provided that the disclosure is
21 approved by an institutional review board or privacy board of the
22 department as authorized by the federal privacy requirements
23 adopted under the Health Insurance Portability and Accountability
24 Act of 1996 (Pub. L. No. 104-191) contained in 45 C.F.R. Part 160
25 and 45 C.F.R. Part 164, Subparts A and E.

26 (c) Notwithstanding other law, reports, records, and
27 information that do not identify a child or the family of a child

1 may be released without consent if the disclosure is for:

2 (1) statistical purposes;

3 (2) purposes related to obtaining or maintaining
4 certification, approval, or quality assurance for the department's
5 laboratory or a public or private laboratory to perform newborn
6 screening tests;

7 (3) purposes relating to review, quality assurance, or
8 improvement of the department's newborn screening under this
9 subchapter or the department's newborn screening program services
10 under Subchapter C;

11 (4) research purposes, provided that the disclosure is
12 approved by an institutional review board or privacy board of the
13 department; or

14 (5) quality assurance related to equipment and
15 supplies, provided that:

16 (A) the assessment is performed by a person who
17 is not a laboratory;

18 (B) only newborn screening specimens are
19 disclosed; and

20 (C) the disclosure is approved by an
21 institutional review board or privacy board of the department.

22 (d) A state officer or employee, a department contractor, or
23 a department contractor's employee, officer, director, or
24 subcontractor may not be examined in a civil, criminal, special, or
25 other judicial or administrative proceeding as to the existence or
26 contents of records, reports, or information made confidential by
27 this section unless disclosure is authorized by this section.

1 SECTION 4. (a) The speaker of the house of representatives
2 shall charge a committee of members selected by the speaker or a
3 house standing committee to conduct an interim study on newborn
4 screening in this state.

5 (b) The committee designated under Subsection (a) of this
6 section shall:

7 (1) study the time frame and procedures for the
8 disclosure required by Chapter 33, Health and Safety Code, to the
9 parent, managing conservator, or guardian of a newborn child;

10 (2) analyze whether procedures should be developed by
11 the Department of State Health Services to provide confirmation to
12 a parent, managing conservator, or guardian of a newborn child that
13 a stored specimen has been destroyed as required by a written
14 statement submitted by the parent, managing conservator, or
15 guardian; and

16 (3) study standardization of the disclosure process
17 for health care facilities in this state.

18 (c) Not later than December 15, 2010, the committee
19 designated under Subsection (a) of this section shall file a report
20 on the results of the interim study conducted under this section
21 with both houses of the legislature.

22 SECTION 5. As soon as practicable after the effective date
23 of this Act, the Department of State Health Services shall
24 implement Section 33.0021, Health and Safety Code, as added by this
25 Act.

26 SECTION 6. As soon as practicable after the effective date
27 of this Act, the Department of State Health Services shall develop

1 the disclosure statement required by Section 33.0111, Health and
2 Safety Code, as added by this Act. The department shall modify an
3 existing form for use for purposes of that section.

4 SECTION 7. This Act takes effect immediately if it receives
5 a vote of two-thirds of all the members elected to each house, as
6 provided by Section 39, Article III, Texas Constitution. If this
7 Act does not receive the vote necessary for immediate effect, this
8 Act takes effect September 1, 2009.