

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 in 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 used; and

(2) that the parent, managing conservator, or guardian

1 may limit the use of the genetic material by providing to the
2 department in accordance with Section 33.0112 a written statement
3 prohibiting the department or laboratory from retaining the genetic
4 material or using the genetic material for any purpose other than
5 the conduct of newborn screening tests authorized under this
6 chapter.

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

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

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

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

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

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

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

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

1 (c) At the time a newborn child is subjected to screening
2 tests under Section 33.011, the physician attending a newborn child
3 or the person attending the delivery of a newborn child that is not
4 attended by a physician shall provide the parent, managing
5 conservator, or guardian of a newborn child a copy of the written
6 disclosure statement developed by the department under this
7 section.

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

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

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

27 (c) An adult individual may file with the department a

1 written statement instructing the department or a laboratory
2 established or approved by the department to destroy any genetic
3 material of the individual that is retained and used under this
4 chapter.

5 SECTION 3. Subchapter B, Chapter 33, Health and Safety
6 Code, is amended by adding Section 33.017 to read as follows:

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

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

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

18 (2) with the consent of each identified individual or
19 an individual authorized to consent on behalf of an identified
20 child;

21 (3) as authorized by court order;

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

24 (5) to public health programs of the department for
25 public health research purposes provided that the disclosure is
26 approved by an institutional review board or privacy board of the
27 department as authorized by the federal privacy requirements

1 adopted under the Health Insurance Portability and Accountability
2 Act of 1996 (Pub. L. No. 104-191) contained in 45 C.F.R. Part 160
3 and 45 C.F.R. Part 164, Subparts A and E.

4 (c) Notwithstanding other law, reports, records, and
5 information that do not identify a child or the family of a child
6 may be released without consent if the disclosure is for:

7 (1) statistical purposes;

8 (2) purposes related to obtaining or maintaining
9 certification, approval, or quality assurance for the department's
10 laboratory or a public or private laboratory to perform newborn
11 screening tests;

12 (3) purposes relating to review, quality assurance, or
13 improvement of the department's newborn screening under this
14 chapter or the department's newborn screening program services
15 under Subchapter C;

16 (4) research purposes, provided that the disclosure is
17 approved by an institutional review board or privacy board of the
18 department; or

19 (5) quality assurance related to equipment and
20 supplies, provided that:

21 (A) the assessment is performed by a person who
22 is not a laboratory;

23 (B) only newborn screening specimens are
24 disclosed; and

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

27 (d) A state officer or employee, a department contractor, or

1 a department contractor's employee, officer, director, or
2 subcontractor may not be examined in a civil, criminal, special, or
3 other judicial or administrative proceeding as to the existence or
4 contents of records, reports, or information made confidential by
5 this section unless disclosure is authorized by this section.

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

10 (b) The committee designated under Subsection (a) of this
11 section shall:

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

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

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

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

27 SECTION 5. As soon as practicable after the effective date

1 of this Act, the Department of State Health Services shall
2 implement Section 33.0021, Health and Safety Code, as added by this
3 Act.

4 SECTION 6. As soon as practicable after the effective date
5 of this Act, the Department of State Health Services shall develop
6 the disclosure statement required by Section 33.0111, Health and
7 Safety Code, as added by this Act. The department shall modify an
8 existing form for use for purposes of that section.

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

President of the Senate

Speaker of the House

I certify that H.B. No. 1672 was passed by the House on April 8, 2009, by the following vote: Yeas 141, Nays 4, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 1672 on May 18, 2009, by the following vote: Yeas 143, Nays 0, 2 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 1672 was passed by the Senate, with amendments, on May 15, 2009, by the following vote: Yeas 29, Nays 1.

Secretary of the Senate

APPROVED: _____

Date

Governor