

1-1 By: Crownover, et al. (Senate Sponsor - Deuell) H.B. No. 1672
1-2 (In the Senate - Received from the House April 8, 2009;
1-3 April 15, 2009, read first time and referred to Committee on Health
1-4 and Human Services; May 11, 2009, reported adversely, with
1-5 favorable Committee Substitute by the following vote: Yeas 8,
1-6 Nays 0; May 11, 2009, sent to printer.)

1-7 COMMITTEE SUBSTITUTE FOR H.B. No. 1672 By: Deuell

1-8 A BILL TO BE ENTITLED
1-9 AN ACT

1-10 relating to newborn screening.

1-11 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-12 SECTION 1. Subchapter A, Chapter 33, Health and Safety
1-13 Code, is amended by adding Section 33.0021 to read as follows:

1-14 Sec. 33.0021. SICKLE-CELL TRAIT. Notwithstanding any
1-15 provision of this chapter, the department shall include sickle-cell
1-16 trait in the detection and treatment program established under this
1-17 chapter, in the screening for heritable diseases conducted under
1-18 Subchapter B, and in the newborn screening services provided under
1-19 Subchapter C.

1-20 SECTION 2. Subchapter B, Chapter 33, Health and Safety
1-21 Code, is amended by adding Sections 33.0111 and 33.0112 to read as
1-22 follows:

1-23 Sec. 33.0111. DISCLOSURE. (a) The department shall
1-24 develop a disclosure statement that clearly discloses to the
1-25 parent, managing conservator, or guardian of a newborn child
1-26 subjected to screening tests under Section 33.011:

1-27 (1) that the department or a laboratory established or
1-28 approved by the department under Section 33.016 may retain for use
1-29 by the department or laboratory genetic material used to conduct
1-30 the newborn screening tests and discloses how the material is
1-31 managed and used; and

1-32 (2) that the parent, managing conservator, or guardian
1-33 may limit the use of the genetic material by providing to the
1-34 department in accordance with Section 33.0112 a written statement
1-35 prohibiting the department or laboratory from retaining the genetic
1-36 material or using the genetic material for any purpose other than
1-37 the conduct of newborn screening tests authorized under this
1-38 chapter.

1-39 (b) The disclosure statement required by Subsection (a)
1-40 must be included on the form developed by the department to inform
1-41 parents about newborn screening. The disclosure statement must:

1-42 (1) be on a separate sheet of the form;

1-43 (2) be presented together with the written statement
1-44 described by Subsection (a)(2) in a format that allows a parent,
1-45 managing conservator, or guardian of a newborn child to either:

1-46 (A) sign, detach, and mail a portion of the form
1-47 to the department to require the department or laboratory to
1-48 destroy the genetic material on completion of the newborn screening
1-49 tests; or

1-50 (B) check a box and sign next to the box on the
1-51 form a statement indicating the parent, managing conservator, or
1-52 guardian is requiring the department or laboratory to destroy the
1-53 genetic material on completion of the newborn screening tests;

1-54 (3) include instructions on how to complete the
1-55 portions of the form described by Subdivisions (2)(A) and (B);

1-56 (4) include the department's mailing address; and

1-57 (5) be made available to a parent, managing
1-58 conservator, or guardian of a newborn child through alternative
1-59 sources.

1-60 (c) At the time a newborn child is subjected to screening
1-61 tests under Section 33.011, the physician attending a newborn child
1-62 or the person attending the delivery of a newborn child that is not
1-63 attended by a physician shall provide the parent, managing

2-1 conservator, or guardian of a newborn child a copy of the written
 2-2 disclosure statement developed by the department under this
 2-3 section.

2-4 (d) The department shall establish procedures for a
 2-5 physician attending a newborn child or the person attending the
 2-6 delivery of a newborn child to provide verification to the
 2-7 department that the physician or person has provided the parent,
 2-8 managing conservator, or guardian of the newborn child the
 2-9 disclosure required under this section.

2-10 Sec. 33.0112. STATEMENT PROHIBITING RETENTION OF GENETIC
 2-11 MATERIAL. (a) A parent, managing conservator, or guardian of a
 2-12 newborn child may file with the department a signed written
 2-13 statement prohibiting the department or a laboratory established or
 2-14 approved by the department from retaining any genetic material
 2-15 related to the newborn screening tests conducted under this chapter
 2-16 or using the genetic material for any purpose other than the conduct
 2-17 of the newborn screening tests. A parent, managing conservator, or
 2-18 guardian may file the written statement on a form provided by the
 2-19 department.

2-20 (b) Not later than the 60th day after the department
 2-21 receives the written statement, the department or laboratory shall
 2-22 destroy the genetic material used in the screening tests.

2-23 (c) An adult individual may file with the department a
 2-24 written statement instructing the department or a laboratory
 2-25 established or approved by the department to destroy any genetic
 2-26 material of the individual that is retained and used under this
 2-27 chapter.

2-28 SECTION 3. Subchapter B, Chapter 33, Health and Safety
 2-29 Code, is amended by adding Section 33.017 to read as follows:

2-30 Sec. 33.017. CONFIDENTIALITY. (a) Reports, records, and
 2-31 information obtained or developed by the department under this
 2-32 chapter are confidential and are not subject to disclosure under
 2-33 Chapter 552, Government Code, are not subject to subpoena, and may
 2-34 not otherwise be released or made public except as provided by this
 2-35 section.

2-36 (b) Notwithstanding other law, reports, records, and
 2-37 information obtained or developed by the department under this
 2-38 chapter may be disclosed:

2-39 (1) for purposes of diagnosis or follow-up authorized
 2-40 under Section 33.014;

2-41 (2) with the consent of each identified individual or
 2-42 an individual authorized to consent on behalf of an identified
 2-43 child;

2-44 (3) as authorized by court order;

2-45 (4) to a medical examiner authorized to conduct an
 2-46 autopsy on a child or an inquest on the death of a child; or

2-47 (5) to public health programs of the department for
 2-48 public health research purposes provided that the disclosure is
 2-49 approved by an institutional review board or privacy board of the
 2-50 department as authorized by the federal privacy requirements
 2-51 adopted under the Health Insurance Portability and Accountability
 2-52 Act of 1996 (Pub. L. No. 104-191) contained in 45 C.F.R. Part 160
 2-53 and 45 C.F.R. Part 164, Subparts A and E.

2-54 (c) Notwithstanding other law, reports, records, and
 2-55 information that do not identify a child or the family of a child
 2-56 may be released without consent if the disclosure is for:

2-57 (1) statistical purposes;

2-58 (2) purposes related to obtaining or maintaining
 2-59 certification, approval, or quality assurance for the department's
 2-60 laboratory or a public or private laboratory to perform newborn
 2-61 screening tests;

2-62 (3) purposes relating to review, quality assurance, or
 2-63 improvement of the department's newborn screening under this
 2-64 chapter or the department's newborn screening program services
 2-65 under Subchapter C;

2-66 (4) research purposes, provided that the disclosure is
 2-67 approved by an institutional review board or privacy board of the
 2-68 department; or

2-69 (5) quality assurance related to equipment and

3-1 supplies, provided that:
 3-2 (A) the assessment is performed by a person who
 3-3 is not a laboratory;
 3-4 (B) only newborn screening specimens are
 3-5 disclosed; and
 3-6 (C) the disclosure is approved by an
 3-7 institutional review board or privacy board of the department.
 3-8 (d) A state officer or employee, a department contractor, or
 3-9 a department contractor's employee, officer, director, or
 3-10 subcontractor may not be examined in a civil, criminal, special, or
 3-11 other judicial or administrative proceeding as to the existence or
 3-12 contents of records, reports, or information made confidential by
 3-13 this section unless disclosure is authorized by this section.

3-14 SECTION 4. (a) The speaker of the house of representatives
 3-15 shall charge a committee of members selected by the speaker or a
 3-16 house standing committee to conduct an interim study on newborn
 3-17 screening in this state.

3-18 (b) The committee designated under Subsection (a) of this
 3-19 section shall:

3-20 (1) study the time frame and procedures for the
 3-21 disclosure required by Chapter 33, Health and Safety Code, to the
 3-22 parent, managing conservator, or guardian of a newborn child;

3-23 (2) analyze whether procedures should be developed by
 3-24 the Department of State Health Services to provide confirmation to
 3-25 a parent, managing conservator, or guardian of a newborn child that
 3-26 a stored specimen has been destroyed as required by a written
 3-27 statement submitted by the parent, managing conservator, or
 3-28 guardian; and

3-29 (3) study standardization of the disclosure process
 3-30 for health care facilities in this state.

3-31 (c) Not later than December 15, 2010, the committee
 3-32 designated under Subsection (a) of this section shall file a report
 3-33 on the results of the interim study conducted under this section
 3-34 with both houses of the legislature.

3-35 SECTION 5. As soon as practicable after the effective date
 3-36 of this Act, the Department of State Health Services shall
 3-37 implement Section 33.0021, Health and Safety Code, as added by this
 3-38 Act.

3-39 SECTION 6. As soon as practicable after the effective date
 3-40 of this Act, the Department of State Health Services shall develop
 3-41 the disclosure statement required by Section 33.0111, Health and
 3-42 Safety Code, as added by this Act. The department shall modify an
 3-43 existing form for use for purposes of that section.

3-44 SECTION 7. This Act takes effect immediately if it receives
 3-45 a vote of two-thirds of all the members elected to each house, as
 3-46 provided by Section 39, Article III, Texas Constitution. If this
 3-47 Act does not receive the vote necessary for immediate effect, this
 3-48 Act takes effect September 1, 2009.

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