

House Bill 1672
Senate Amendments
Section-by-Section Analysis

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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 guardian may limit the use of the genetic material by providing to the department in accordance with Section 33.0112 a written statement prohibiting the department or

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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 may limit the use of the genetic material by providing to the department in accordance with Section 33.0112 a written statement prohibiting the department or

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laboratory from retaining the genetic material.

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

The disclosure statement must:

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

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

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

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

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

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

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

(c) At the time a newborn child is subjected to screening

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laboratory from retaining the genetic material or using the genetic material for any purpose other than the conduct of newborn screening tests authorized under this chapter.

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

The disclosure statement must:

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

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

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

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

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

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

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

(c) At the time a newborn child is subjected to screening

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tests under Section 33.011, the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall provide the parent, managing conservator, or guardian of a newborn child a copy of the written disclosure statement developed by the department under this section.

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

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

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

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tests under Section 33.011, the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall provide the parent, managing conservator, or guardian of a newborn child a copy of the written disclosure statement developed by the department under this section.

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

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

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

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screening tests.

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

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

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

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

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

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

(3) as authorized by court order;

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

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screening tests.

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

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

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

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

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

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

(3) as authorized by court order;

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

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

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

(1) statistical purposes;

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

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

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

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

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

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

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

(1) statistical purposes;

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

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

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

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

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

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(B) only newborn screening specimens are disclosed;
and
(C) the disclosure is approved by an institutional review board or privacy board of the department.
(d) A state officer or employee, a department contractor, or a department contractor's employee, officer, director, or subcontractor may not be examined in a civil, criminal, special, or other judicial or administrative proceeding as to the existence or contents of records, reports, or information made confidential by this section unless disclosure is authorized by this section.

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

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

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

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

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(B) only newborn screening specimens are disclosed;
and
(C) the disclosure is approved by an institutional review board or privacy board of the department.
(d) A state officer or employee, a department contractor, or a department contractor's employee, officer, director, or subcontractor may not be examined in a civil, criminal, special, or other judicial or administrative proceeding as to the existence or contents of records, reports, or information made confidential by this section unless disclosure is authorized by this section.

Same as House version.

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submitted by the parent, managing conservator, or guardian; and

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

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

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

Same as House version.

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

Same as House version.

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

Same as House version.

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September 1, 2009.