

Amend **CSHB 411** (senate committee printing) as follows:

(1) In the recital to SECTION 1 of the bill (page 1, line 15), strike "and (i)" and substitute "(i), and (j)".

(2) In SECTION 1 of the bill, strike amended Sections 33.017(b) and (c), Health and Safety Code (page 1, line 35, through page 2, line 27), and substitute the following:

(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; ~~[or]~~

(5) to public health programs of the department for public health research purposes, provided that the disclosure is approved by:

(A) the commissioner or the commissioner's designee; and

(B) 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;

(6) for purposes relating to review or quality assurance of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C, provided that no disclosure occurs outside of the department's newborn screening program;

(7) for purposes related to obtaining or maintaining federal certification, including related quality assurance, for the department's laboratory, provided that no disclosure occurs outside of the department's newborn screening program; or

(8) for purposes relating to improvement of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C, provided that the disclosure is approved by the commissioner or the commissioner's designee.

(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 federal certification, including related review and [approval, or] quality assurance:

(A) for the department's laboratory that require disclosure outside of the department's newborn screening program;
or

(B) for a public or private laboratory to perform newborn screening tests that are not part of inter-laboratory exchanges required for federal certification of the department's laboratory, provided that the disclosure is approved by the commissioner or the commissioner's designee; or

(3) other ~~[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 purposes related to public

health testing equipment and supplies, provided that the disclosure is approved by:

(A) the commissioner or the commissioner's designee [~~assessment is performed by a person who is not a laboratory~~]; and

(B) [~~only newborn screening specimens are disclosed~~]; and

[~~(C) the disclosure is approved by~~] an institutional review board or privacy board of the department.

(3) In SECTION 1 of the bill, in added Section 33.017(c-1), Health and Safety Code (page 2, line 30), between "public health research purposes" and "if", insert "not described by Subsection (b)(5)".

(4) In SECTION 1 of the bill, in added Section 33.017(c-1)(1), Health and Safety Code (page 2, line 31), strike "a parent" and substitute "a parent, managing conservator, or guardian".

(5) In SECTION 1 of the bill, in added Section 33.017(e), Health and Safety Code (page 2, line 39), strike "Subsection (c)(4)" and substitute "Subsection (c)(3)".

(6) In SECTION 1 of the bill, in added Section 33.017(g), Health and Safety Code (page 2, line 53), strike "approves" and substitute "reviews a potential".

(7) In SECTION 1 of the bill, strike added Sections 33.017(h) and (i), Health and Safety Code (page 2, lines 56-66), and substitute the following:

(h) Nothing in this section affects the requirement that screening tests be performed under Section 33.011.

(i) If a parent, managing conservator, or guardian of a child consents to disclosure under this section:

(1) the parent, managing conservator, or guardian who consented to the disclosure may revoke the consent, in writing, at any time by using a form designated by the department; and

(2) the child may revoke the consent, in writing, at any time on or after the date the child attains the age of majority by using a form designated by the department.

(j) If a person revokes consent under Subsection (i), the department shall destroy any genetic material obtained from the child as provided by Section 33.0112.

(8) In SECTION 2 of the bill, strike Subsection (b) (page 3, lines 4-5) and substitute the following:

(b) The changes made to Sections 33.0111 and 33.0112, Health and Safety Code, as amended by this Act, and Section 33.017(c-1), as added by this Act, take effect June 1, 2012.

(9) Add the following appropriately numbered SECTIONS to the bill and renumber SECTIONS of the bill accordingly:

SECTION _____. The heading to Section 33.0111, Health and Safety Code, is amended to read as follows:

Sec. 33.0111. DISCLOSURE STATEMENT AND CONSENT.

SECTION _____. Section 33.0111, Health and Safety Code, is amended by amending Subsections (a), (b), and (d) and adding Subsections (e), (f), and (g) to read as follows:

(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 subject to this section and Sections 33.0112 and 33.017; and

(2) that reports, records, and information obtained by

the department under this chapter that do not identify a child or the family of a child will not be released for public health research purposes under Section 33.017(c-1) unless a parent, managing conservator, or guardian of the child consents to disclosure; and

(3) that newborn screening blood spots and associated data are confidential under law and may only be used as described by Section 33.017 ~~[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 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 consent to disclosure under Section 33.017(c-1) ~~[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];~~

(2) ~~[(3)]~~ include instructions on how to complete the portions of the form described by Subdivision (1) ~~[Subdivisions (2)(A) and (B)]~~;

(3) ~~[(4)]~~ include the department's mailing address; and

(4) describe how ~~[(5) be made available to]~~ a parent, managing conservator, or guardian of a newborn child may obtain information regarding consent through alternative sources.

(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 statement required under this section.

(e) The physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall submit any document required by the department.

(f) This section does not supersede the requirements imposed by Section 33.017.

(g) A reference in this section to Section 33.017 means Section 33.017 as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009.

SECTION _____. Section 33.0112, Health and Safety Code, is amended to read as follows:

Sec. 33.0112. DESTRUCTION ~~[STATEMENT PROHIBITING RETENTION]~~ OF GENETIC MATERIAL. (a) The department shall destroy any genetic material obtained from a child under this chapter not later than the second anniversary of the date the department receives the genetic material unless a parent, managing

conservator, or guardian of the child consents to disclosure under Section 33.017(c-1) ~~[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) The department shall destroy any genetic material obtained from a child under this chapter not later than the second anniversary of the date the department receives the genetic material if:

(1) a parent, managing conservator, or guardian of the child consents to disclosure under Section 33.017(c-1);

(2) the parent, managing conservator, or guardian who consented to the disclosure revokes the consent under Section 33.017(i); and

(3) the department receives the written revocation of consent under Section 33.017(i) not later than the second anniversary of the date the department received the genetic material ~~[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 screening tests]~~.

(c) The department shall destroy any genetic material obtained from a child under this chapter not later than the 60th day after the date the department receives a written revocation of consent under Section 33.017(i) if:

(1) a parent, managing conservator, or guardian of the child consented to disclosure under Section 33.017(c-1);

(2) the parent, managing conservator, or guardian who consented to the disclosure or the child revokes the consent under Section 33.017(i); and

(3) the department receives the written revocation of consent later than the second anniversary of the date the department received the genetic material ~~[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]~~.

(d) A reference in this section to Section 33.017 means Section 33.017 as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009.