

SENATE AMENDMENTS

2nd Printing

By: Laubenberg, Crownover

H.B. No. 411

A BILL TO BE ENTITLED

AN ACT

relating to the confidentiality of newborn screening information.

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

SECTION 1. Section 33.017, Health and Safety Code, as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009, is amended by amending Subsections (a), (b), and (c) and adding Subsections (a-1), (c-1), (e), (f), (g), and (h) to read as follows:

(a) In this section:

(1) "Affiliated with a health agency" means a person who is an employee or former employee of a health agency.

(2) "Commission" means the Health and Human Services Commission.

(3) "Commissioner" means the commissioner of state health services.

(4) "Health agency" means the commission and the health and human services agencies listed in Section 531.001, Government Code.

(5) "Public health purpose" means a purpose that relates to cancer, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening.

(a-1) 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,

1 are not subject to subpoena, and may not otherwise be released or
2 made public except as provided by this section.

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

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

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

11 (3) as authorized by court order;

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

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

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

19 (B) an institutional review board or privacy
20 board of the department as authorized by the federal privacy
21 requirements adopted under the Health Insurance Portability and
22 Accountability Act of 1996 (Pub. L. No. 104-191) contained in 45
23 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E.

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

27 (1) statistical purposes;

1 (2) purposes related to obtaining or maintaining
2 federal certification, including related [~~approval, or~~] quality
3 assurance, for:

4 (A) the department's laboratory; or

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

10 (3) purposes relating to:

11 (A) review or [~~or~~] quality assurance [~~or~~
12 ~~improvement~~] of the department's newborn screening under this
13 chapter or the department's newborn screening program services
14 under Subchapter C; or

15 (B) improvement of the department's newborn
16 screening under this chapter or the department's newborn screening
17 program services under Subchapter C, provided that the disclosure
18 is approved by the commissioner or the commissioner's designee; or

19 (4) other [~~research purposes, provided that the~~
20 ~~disclosure is approved by an institutional review board or privacy~~
21 ~~board of the department, or~~

22 [~~5~~] quality assurance purposes related to public
23 health testing equipment and supplies, provided that the disclosure
24 is approved by:

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

1 (B) [~~only newborn screening specimens are~~
2 ~~disclosed, and~~

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

5 (c-1) Notwithstanding other law, reports, records, and
6 information that do not identify a child or the family of a child
7 may be released for public health research purposes if:

8 (1) a parent of the child consents to the disclosure;
9 and

10 (2) the disclosure is approved by:

11 (A) an institutional review board or privacy
12 board of the department; and

13 (B) the commissioner or the commissioner's
14 designee.

15 (e) If disclosure is approved by the commissioner or the
16 commissioner's designee under Subsection (c)(4) or (c-1), the
17 department shall post notice on the newborn screening web page on
18 the department's Internet website that disclosure has been
19 approved. The commissioner shall determine the form and content of
20 the notice.

21 (f) In accordance with this section, the commissioner or the
22 commissioner's designee:

23 (1) may approve disclosure of reports, records, or
24 information obtained or developed under this chapter only for a
25 public health purpose; and

26 (2) may not approve disclosure of reports, records, or
27 information obtained or developed under this chapter for purposes

1 related to forensic science or health insurance underwriting.

2 (g) An institutional review board or privacy board of the
3 department that approves disclosure under this section must include
4 at least three persons who are not affiliated with a health agency,
5 one of whom must be a member of the public.

6 (h) The requirement that consent be obtained before certain
7 disclosures of reports, records, or information may be made under
8 this section does not affect the requirement that screening tests
9 be performed under Section 33.011.

10 SECTION 2. This Act takes effect immediately if it receives
11 a vote of two-thirds of all the members elected to each house, as
12 provided by Section 39, Article III, Texas Constitution. If this
13 Act does not receive the vote necessary for immediate effect, this
14 Act takes effect September 1, 2011.

ADOPTED

MAY 23 2011

Atty. Gen.
Secretary of the Senate

By: LAUBENBERG

H.B. No. 411

Substitute the following for H.B. No. 411 :

By: *Dewell*

C.S. H.B. No. 411

A BILL TO BE ENTITLED

AN ACT

relating to the confidentiality of newborn screening information.

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

SECTION 1. Section 33.017, Health and Safety Code, as added by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular Session, 2009, is amended by amending Subsections (a), (b), and (c) and adding Subsections (a-1), (c-1), (e), (f), (g), (h), and (i) to read as follows:

(a) In this section:

(1) "Affiliated with a health agency" means a person who is an employee or former employee of a health agency.

(2) "Commission" means the Health and Human Services Commission.

(3) "Commissioner" means the commissioner of state health services.

(4) "Health agency" means the commission and the health and human services agencies listed in Section 531.001, Government Code.

(5) "Public health purpose" means a purpose that relates to cancer, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening.

(a-1) 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; 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.

(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 [~~, approval, or~~] quality assurance, for:

(A) the department's laboratory; or

(B) 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;

(3) purposes relating to:

(A) review or [~~7~~] quality assurance [~~, or improvement~~] of the department's newborn screening under this chapter or the department's newborn screening program services under Subchapter C; or

(B) 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; or

(4) other [~~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.

(c-1) Notwithstanding other law, reports, records, and
information that do not identify a child or the family of a child
may be released for public health research purposes if:

(1) a parent of the child consents to the disclosure;
and

(2) the disclosure is approved by:

(A) an institutional review board or privacy board
of the department; and

(B) the commissioner or the commissioner's
designee.

(e) If disclosure is approved by the commissioner or the
commissioner's designee under Subsection (c)(4) or (c-1), the
department shall post notice on the newborn screening web page on
the department's Internet website that disclosure has been
approved. The commissioner shall determine the form and content of
the notice.

(f) In accordance with this section, the commissioner or the

commissioner's designee:

(1) may approve disclosure of reports, records, or information obtained or developed under this chapter only for a public health purpose; and

(2) may not approve disclosure of reports, records, or information obtained or developed under this chapter for purposes related to forensic science or health insurance underwriting.

(g) An institutional review board or privacy board of the department that approves disclosure under this section must include at least three persons who are not affiliated with a health agency, one of whom must be a member of the public.

(h) The requirement that consent be obtained before certain disclosures of reports, records, or information may be made under this section does not affect the requirement that screening tests be performed under Section 33.011.

(i) If a parent of a child consents to disclosure under this section:

(1) a parent of the child may revoke the consent, in whole or in part, at any time; and

(2) the child may revoke the consent, in whole or in part, at any time on or after the date the child attains the age of majority.

SECTION 2. (a) Except as provided by Subsection (b) of this section, 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 September 1, 2011.

(b) Section 33.017(c-1), Health and Safety Code, as added by this Act, takes effect June 1, 2012.

ADOPTED

MAY 23 2011

Atay Spaw
Secretary of the Senate

FLOOR AMENDMENT NO. 1

BY: *Demell*

1 Amend C.S.H.B. No. 411 (senate committee printing) as
2 follows:

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

5 (2) In SECTION 1 of the bill, strike amended Sections
6 33.017(b) and (c), Health and Safety Code (page 1, line 35, through
7 page 2, line 27), and substitute the following:

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:

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

24 (B) an institutional review board or privacy
25 board of the department as authorized by the federal privacy
26 requirements adopted under the Health Insurance Portability and
27 Accountability Act of 1996 (Pub. L. No. 104-191) contained in 45
28 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E;

29 (6) for purposes relating to review or quality

1 assurance of the department's newborn screening under this chapter
2 or the department's newborn screening program services under
3 Subchapter C, provided that no disclosure occurs outside of the
4 department's newborn screening program;

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

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

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

17 (1) statistical purposes;

18 (2) purposes related to obtaining or maintaining
19 federal certification, including related review and [approval, or]
20 quality assurance:

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

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

29 (3) other [purposes relating to review, quality
30 assurance, or improvement of the department's newborn screening
31 under this chapter or the department's newborn screening program

1 ~~services under Subchapter C,~~

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

5 ~~[(5)]~~ quality assurance purposes related to public
6 health testing equipment and supplies, provided that the disclosure
7 is approved by:

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

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

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

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

19 (4) In SECTION 1 of the bill, in added Section
20 33.017(c-1)(1), Health and Safety Code (page 2, line 31), strike "a
21 parent" and substitute "a parent, managing conservator, or
22 guardian".

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

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

29 (7) In SECTION 1 of the bill, strike added Sections
30 33.017(h) and (i), Health and Safety Code (page 2, lines 56-66), and
31 substitute the following:

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

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

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

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

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

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

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

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

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

23 Sec. 33.0111. DISCLOSURE STATEMENT AND CONSENT.

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

27 (a) The department shall develop a disclosure statement
28 that clearly discloses to the parent, managing conservator, or
29 guardian of a newborn child subjected to screening tests under
30 Section 33.011:

31 (1) that the department or a laboratory established or

1 approved by the department under Section 33.016 may retain for use
2 by the department or laboratory genetic material used to conduct
3 the newborn screening tests and discloses how the material is
4 managed and used subject to this section and Sections 33.0112 and
5 33.017; and

6 (2) that reports, records, and information obtained by
7 the department under this chapter that do not identify a child or
8 the family of a child will not be released for public health
9 research purposes under Section 33.017(c-1) unless a parent,
10 managing conservator, or guardian of the child consents to
11 disclosure; and

12 (3) that newborn screening blood spots and associated
13 data are confidential under law and may only be used as described by
14 Section 33.017 [~~that the parent, managing conservator, or guardian~~
15 ~~may limit the use of the genetic material by providing to the~~
16 ~~department in accordance with Section 33.0112 a written statement~~
17 ~~prohibiting the department or laboratory from retaining the genetic~~
18 ~~material or using the genetic material for any purpose other than~~
19 ~~the conduct of newborn screening tests authorized under this~~
20 ~~chapter~~].

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

24 (1) [~~be on a separate sheet of the form,~~
25 [~~2~~] be [~~presented together with the written~~
26 ~~statement described by Subsection (a)(2)~~] in a format that allows a
27 parent, managing conservator, or guardian of a newborn child to
28 consent to disclosure under Section 33.017(c-1) [~~either,~~

29 [~~(A) sign, detach, and mail a portion of the form~~
30 ~~to the department to require the department or laboratory to~~
31 ~~destroy the genetic material on completion of the newborn screening~~

1 ~~tests, or~~

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

6 (2) [~~(3)~~] include instructions on how to complete the
7 portions of the form described by Subdivision (1) [~~Subdivisions~~
8 ~~(2)(A) and (B)~~];

9 (3) [~~(4)~~] include the department's mailing address;
10 and

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

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

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

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

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

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

30 Sec. 33.0112. DESTRUCTION [~~STATEMENT~~ ~~PROHIBITING~~
31 ~~RETENTION~~] OF GENETIC MATERIAL. (a) The department shall destroy

1 any genetic material obtained from a child under this chapter not
2 later than the second anniversary of the date the department
3 receives the genetic material unless a parent, managing
4 conservator, or guardian of the child consents to disclosure under
5 Section 33.017(c-1) [A parent, managing conservator, or guardian of
6 a newborn child may file with the department a signed written
7 statement prohibiting the department or a laboratory established or
8 approved by the department from retaining any genetic material
9 related to the newborn screening tests conducted under this chapter
10 or using the genetic material for any purpose other than the conduct
11 of the newborn screening tests. A parent, managing conservator, or
12 guardian may file the written statement on a form provided by the
13 department].

14 (b) The department shall destroy any genetic material
15 obtained from a child under this chapter not later than the second
16 anniversary of the date the department receives the genetic
17 material if:

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

20 (2) the parent, managing conservator, or guardian who
21 consented to the disclosure revokes the consent under Section
22 33.017(i); and

23 (3) the department receives the written revocation of
24 consent under Section 33.017(i) not later than the second
25 anniversary of the date the department received the genetic
26 material [~~Not later than the 60th day after the department receives~~
27 ~~the written statement, the department or laboratory shall destroy~~
28 ~~the genetic material used in the screening tests].~~

29 (c) The department shall destroy any genetic material
30 obtained from a child under this chapter not later than the 60th day
31 after the date the department receives a written revocation of

1 consent under Section 33.017(i) if:

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

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

7 (3) the department receives the written revocation of
8 consent later than the second anniversary of the date the
9 department received the genetic material [~~An adult individual may~~
10 ~~file with the department a written statement instructing the~~
11 ~~department or a laboratory established or approved by the~~
12 ~~department to destroy any genetic material of the individual that~~
13 ~~is retained and used under this chapter].~~

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

ADOPTED

MAY 23 2011



FLOOR AMENDMENT NO. 2

BY: Atay Spaul
Secretary of the Senate

1 Amend C.S.H.B. No. 411 (senate committee printing) by
2 adding the following appropriately numbered SECTIONS to the bill
3 and renumbering subsequent SECTIONS of the bill accordingly:

4 SECTION __. Subdivision (2), Section 47.001, Health and
5 Safety Code, is amended to read as follows:

6 (2) "Birthing facility" means:

7 (A) a hospital licensed under Chapter 241 that
8 offers obstetrical services [~~and is located in a county with a~~
9 ~~population of more than 50,000~~]; [~~or~~]

10 (B) a birthing center licensed under Chapter
11 244;

12 (C) a children's hospital; or

13 (D) a facility, maintained or operated by this
14 state or an agency of this state, that provides obstetrical
15 services [~~that is located in a county with a population of more~~
16 ~~than 50,000 and that has 100 or more births per year~~].

17 SECTION __. Section 47.003, Health and Safety Code, is
18 amended by amending Subsections (a), (c), (d), and (e) and
19 adding Subsections (a-1) and (f) to read as follows:

20 (a) A birthing facility, through a program certified by
21 the department under Section 47.004, shall perform, either
22 directly or through a transfer agreement, [~~offer the parents of~~
23 ~~a newborn~~] a hearing screening [~~for the newborn~~] for the
24 identification of hearing loss on each newborn or infant born at
25 the facility before the newborn or infant is discharged from the
26 facility unless:

27 (1) the parent declines the screening;

28 (2) the newborn or infant is transferred to another
29 facility before the screening is performed; or

30 (3) the screening has previously been completed.

1 (a-1) The birthing facility [screening] shall inform the
2 parents [be offered] during [the birth] admission that:

3 (1) the facility is required by law to screen a
4 newborn or infant for hearing loss; and

5 (2) the parents may decline the screening[, and the
6 parents shall be informed that information may be provided to
7 the department upon their written consent].

8 (c) Subject to Section 47.008, the [The] department shall
9 [may] maintain data and information on each newborn or infant
10 who receives a hearing screening under Subsection (a) [services
11 under a program].

12 (d) The department shall ensure that intervention is
13 available to families for a newborn or infant identified as
14 having hearing loss and that the intervention is managed by
15 state programs operating under the Individuals with Disabilities
16 Education Act (20 U.S.C. Section 1400 et seq.).

17 (e) The department shall ensure that the intervention
18 described by Subsection (d) is available for a newborn or infant
19 identified as having hearing loss not later than the sixth month
20 after the newborn's or infant's birth and through the time the
21 child is an infant unless the infant has been hospitalized since
22 birth.

23 (f) If a newborn or an infant receives medical
24 intervention services, including a hearing aid or cochlear
25 implant, the intervention specialist shall report the results of
26 the intervention to the department.

27 SECTION __. Chapter 47, Health and Safety Code, is amended
28 by adding Section 47.0031 to read as follows:

29 Sec. 47.0031. FOLLOW-UP SCREENING. (a) The program that
30 performed the hearing screening under Section 47.003 shall
31 provide the newborn's or infant's parents with the screening
32 results. A birthing facility, through the program, shall offer

1 a follow-up hearing screening to the parents of a newborn or
2 infant who does not pass the screening, or refer the parents to
3 another program for the follow-up hearing screening. The
4 follow-up hearing screening should be performed not later than
5 the 30th day after the date the newborn or infant is discharged
6 from the facility.

7 (b) If a newborn or an infant does not pass the screening
8 in a follow-up hearing screening, the program that performed the
9 follow-up hearing screening on the newborn or infant shall:

10 (1) provide the newborn's or infant's parents with
11 the screening results;

12 (2) assist in scheduling a diagnostic audiological
13 evaluation for the newborn or infant, consistent with the most
14 current guidelines in the Joint Committee on Infant Hearing
15 Position Statement, or refer the newborn or infant to a licensed
16 audiologist who provides diagnostic audiological evaluations for
17 newborns or infants that are consistent with the most current
18 guidelines in the Joint Committee on Infant Hearing Position
19 Statement; and

20 (3) refer the newborn or infant to early childhood
21 intervention services.

22 SECTION __. Subsections (b) and (d), Section 47.004,
23 Health and Safety Code, are amended to read as follows:

24 (b) In order to be certified, the program must:

25 (1) provide hearing screening using equipment
26 recommended by the department;

27 (2) use appropriate staff to provide the screening;

28 (3) maintain and report data electronically as
29 required by the department;

30 (4) distribute family, health care provider, and
31 physician educational materials standardized by the department;

32 [~~and~~]

1 (5) provide information, as recommended by the
2 department, to the parents on follow-up services for newborns
3 and infants who do not pass the [~~with abnormal~~] screening; and

4 (6) be supervised by:

5 (A) a physician;

6 (B) an audiologist;

7 (C) a registered nurse; or

8 (D) a physician assistant [~~results~~].

9 (d) The department may renew the certification of a
10 program on a periodic basis as established by board rule in
11 order to ensure quality services to newborns, infants, and
12 families.

13 SECTION __. Section 47.005, Health and Safety Code, is
14 amended by amending Subsections (a) and (b) and adding
15 Subsections (d) and (e) to read as follows:

16 (a) A birthing facility that operates a program shall
17 distribute to the parents of each newborn or infant who is
18 screened educational materials that are standardized by the
19 department regarding screening results and follow-up care.

20 (b) A birthing facility that operates a program shall
21 report screening results to:

22 (1) the parents;

23 (2) [] the newborn's or infant's attending
24 physician, primary care physician, or other applicable health
25 care provider; [] and

26 (3) the department.

27 (d) The department may coordinate the diagnostic
28 audiological evaluation required under Section 47.0031(b)(2). A
29 diagnostic audiological evaluation must be completed on the
30 newborn or infant:

1 (1) not later than the third month after the
2 newborn's or infant's birth unless the newborn or infant has
3 been hospitalized since birth; or

4 (2) upon referral by the newborn's or infant's
5 primary care physician or other applicable health care provider.

6 (e) An audiologist who performs a diagnostic audiological
7 evaluation under this chapter shall report the results of the
8 evaluation to:

9 (1) the parents;

10 (2) the newborn's or infant's primary care physician
11 or other applicable health care provider; and

12 (3) the department under Section 47.007(b).

13 SECTION __. Section 47.007, Health and Safety Code, is
14 amended by amending Subsection (b) and adding Subsections (d)
15 through (h) to read as follows:

16 (b) Subject to Section 47.008, a [A] qualified hearing
17 screening provider, hospital, health care provider, physician,
18 audiologist, or intervention specialist shall [may] access the
19 information management, reporting, and tracking system to
20 provide information[~~, where available,~~] to the department and
21 may obtain information from the department[~~, including~~
22 information] relating to:

23 (1) the results of each hearing screening performed
24 under Section 47.003(a) or 47.0031(a);

25 (2) the results of each diagnostic audiological
26 evaluation required under Section 47.0031(b) (2);

27 (3) [+1+] infants who receive follow-up care;

28 (4) [+2+] infants identified with hearing loss;

29 (5) [+3+] infants who are referred for intervention
30 services; and

31 (6) [+4+] case level information necessary to report
32 required statistics to:

1 (A) the Maternal and Child Health Bureau on an
2 annual basis; and

3 (B) the federal Centers for Disease Control and
4 Prevention.

5 (d) A birthing facility described by Subsection (a) shall
6 report the resulting information in the format and within the
7 time frame specified by the department.

8 (e) A qualified hearing screening provider, audiologist,
9 intervention specialist, educator, or other person who receives
10 a referral from a program under this chapter shall:

11 (1) provide the services needed by the newborn or
12 infant or refer the newborn or infant to a person who provides
13 the services needed by the newborn or infant; and

14 (2) provide, with the consent of the newborn's or
15 infant's parent, the following information to the department or
16 the department's designee:

17 (A) results of follow-up care;

18 (B) results of audiologic testing of an infant
19 identified with hearing loss; and

20 (C) reports on the initiation of intervention
21 services.

22 (f) A qualified hearing screening provider, audiologist,
23 intervention specialist, educator, or other person who provides
24 services to an infant who is diagnosed with hearing loss shall
25 provide, with the consent of the infant's parent, the following
26 information to the department or the department's designee:

27 (1) results of follow-up care;

28 (2) results of audiologic testing; and

29 (3) reports on the initiation of intervention
30 services.

31 (g) A hospital that provides services under this chapter
32 shall use the information management, reporting, and tracking

1 system described by this section, access to which has been
2 provided to the hospital by the department, to report, with the
3 consent of the infant's parent, the following information to the
4 department or the department's designee:

5 (1) results of all follow-up services for an infant
6 who does not pass the screening described by Section 47.003(a)
7 if the hospital provides the follow-up services; or

8 (2) the name of the provider or facility to which the
9 hospital refers an infant who does not pass the screening
10 described by Section 47.003(a) for follow-up services.

11 (h) Subject to Section 47.008, a qualified hearing
12 screening provider, hospital, health care provider, physician,
13 audiologist, or intervention specialist may obtain information
14 from the department relating to:

15 (1) the results of each hearing screening performed
16 under Section 47.003(a) or 47.0031(a);

17 (2) the results of each diagnostic audiological
18 evaluation required under Section 47.0031(b) (2);

19 (3) infants who receive follow-up care;

20 (4) infants identified with hearing loss; and

21 (5) infants who are referred for intervention
22 services.

23 SECTION __. Chapter 47, Health and Safety Code, is amended
24 by adding Sections 47.010 and 47.011 to read as follows:

25 Sec. 47.010. RULEMAKING. (a) The executive commissioner
26 of the Health and Human Services Commission may adopt rules for
27 the department to implement this chapter.

28 (b) If the executive commissioner adopts rules, the
29 executive commissioner shall consider the most current
30 guidelines established by the Joint Committee on Infant Hearing.

31 Sec. 47.011. DUTIES OF MIDWIFE. (a) In this section,
32 "midwife" has the meaning assigned by Section 203.002,

1 Occupations Code, and includes a nurse midwife described by
2 Section 301.152, Occupations Code.

3 (b) A midwife who attends the birth of a newborn:

4 (1) is not required to offer the parents of the
5 newborn a hearing screening for the newborn for the
6 identification of hearing loss; and

7 (2) shall refer the parents of the newborn to a
8 birthing facility or a provider that participates in the program
9 and make a record of the referral.

10 SECTION __. Section 47.002, Health and Safety Code, is
11 repealed.

12 SECTION __. (a) Not later than January 1, 2012, the
13 executive commissioner of the Health and Human Services
14 Commission shall prescribe a form to document a parent's
15 decision to decline screening under Subdivision (1), Subsection
16 (a), Section 47.003, Health and Safety Code, as added by this
17 Act, in consultation with persons and organizations interested
18 in newborn hearing screening.

19 (b) The Department of State Health Services may post the
20 form prescribed under Subsection (a) of this section on the
21 department's Internet website.

22 (c) A person or facility is not required to comply with
23 the changes in law made by this Act to Chapter 47, Health and
24 Safety Code, until January 1, 2012.

**LEGISLATIVE BUDGET BOARD
Austin, Texas**

FISCAL NOTE, 82ND LEGISLATIVE REGULAR SESSION

May 25, 2011

TO: Honorable Joe Straus, Speaker of the House, House of Representatives

FROM: John S O'Brien, Director, Legislative Budget Board

IN RE: HB411 by Laubenberg (Relating to the confidentiality of newborn screening information.),
As Passed 2nd House

No fiscal implication to the State is anticipated.

The bill would amend Sections 33.017, 33.0111, and 33.0112, Health and Safety Code. The bill would require approval by the commissioner of the Department of State Health Services (DSHS) or the commissioner's designee to disclose newborn screening information under certain circumstances, in addition to the current approval requirements. The bill would allow a parent, managing conservator, or a guardian to give consent to disclosure which may be withdrawn at a later date. The child may also revoke consent once he or she reaches the age of majority. The bill would also require that DSHS post notice on the agency's newborn screening web page when disclosure has been approved. The bill would outline the approved circumstances for releasing newborn screening information, which includes genetic material, for public health research purposes. The bill would also require the genetic material to be destroyed after specific timeframes in certain circumstances.

The bill would amend Chapter 47, Health and Safety Code, to require that newborn or infant hearing screenings be performed at certain birthing facilities unless the parent declines or the screening has already been completed. The bill would require certain reporting of initial and follow-up screening results that is currently authorized but not required. The bill would require that newborn hearing screening programs be supervised by a physician, physician's assistant, audiologist, or registered nurse in order to be certified.

DSHS indicates any cost associated with implementation of the bill could be absorbed within existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 537 State Health Services, Department of

LBB Staff: JOB, CL, VJC, NB, MB

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 82ND LEGISLATIVE REGULAR SESSION

May 18, 2011

TO: Honorable Jane Nelson, Chair, Senate Committee on Health & Human Services

FROM: John S O'Brien, Director, Legislative Budget Board

IN RE: HB411 by Laubenberg (Relating to the confidentiality of newborn screening information.),
Committee Report 2nd House, Substituted

No fiscal implication to the State is anticipated.

The bill would amend Section 33.017, Health and Safety Code by requiring approval by the commissioner of the Department of State Health Services (DSHS) or the commissioner's designee to disclose newborn screening information under certain circumstances, in addition to the current approval requirements. The bill would allow parental consent to disclosure to be withdrawn at a later date. The bill would also require that DSHS post notice on the agency's newborn screening web page when disclosure has been approved. DSHS indicates that implementing the provisions of the bill would have no fiscal impact.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 537 State Health Services, Department of

LBB Staff: JOB, CL, VJC, NB, MB

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 82ND LEGISLATIVE REGULAR SESSION

April 29, 2011

TO: Honorable Jane Nelson, Chair, Senate Committee on Health & Human Services

FROM: John S O'Brien, Director, Legislative Budget Board

IN RE: HB411 by Laubenberg (Relating to the confidentiality of newborn screening information.),
As Engrossed

No fiscal implication to the State is anticipated.

The bill would amend Section 33.017, Health and Safety Code by requiring approval by the commissioner of the Department of State Health Services (DSHS) or the commissioner's designee to disclose newborn screening information under certain circumstances, in addition to the current approval requirements. The bill would also require that DSHS post notice on the agency's newborn screening web page when disclosure has been approved. DSHS indicates that implementing the provisions of the bill would have no fiscal impact.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 537 State Health Services, Department of

LBB Staff: JOB, CL, VJC, NB, MB

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 82ND LEGISLATIVE REGULAR SESSION

March 27, 2011

TO: Honorable Lois W. Kolkhorst, Chair, House Committee on Public Health

FROM: John S O'Brien, Director, Legislative Budget Board

IN RE: HB411 by Laubenberg (Relating to the confidentiality of newborn screening information.),
Committee Report 1st House, Substituted

No fiscal implication to the State is anticipated.

The bill would amend Section 33.017, Health and Safety Code by requiring approval by the commissioner of the Department of State Health Services (DSHS) or the commissioner's designee to disclose newborn screening information under certain circumstances, in addition to the current approval requirements. The bill would also require that DSHS post notice on the agency's newborn screening web page when disclosure has been approved. DSHS indicates that implementing the provisions of the bill would have no fiscal impact.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 537 State Health Services, Department of

LBB Staff: JOB, CL, VJC, NB, MB

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 82ND LEGISLATIVE REGULAR SESSION

February 28, 2011

TO: Honorable Lois W. Kolkhorst, Chair, House Committee on Public Health

FROM: John S O'Brien, Director, Legislative Budget Board

IN RE: HB411 by Laubenberg (Relating to the confidentiality of newborn screening information.),
As Introduced

No fiscal implication to the State is anticipated.

The bill would amend Section 33.017, Health and Safety Code by requiring approval by the commissioner of the Department of State Health Services (DSHS) to disclose newborn screening information under certain circumstances, in addition to the current approval requirements. The bill would also require that DSHS post notice on the agency's newborn screening web page when disclosure has been approved. DSHS indicates that implementing the provisions of the bill would have no fiscal impact.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 537 State Health Services, Department of

LBB Staff: JOB, CL, MB, VJC