

SENATE AMENDMENTS

2nd Printing

By: Crownover, Zerwas, Coleman, Dukes,
Shelton, et al.

H.B. No. 1672

A BILL TO BE ENTITLED

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 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

1 guardian may limit the use of the genetic material by providing to
2 the department in accordance with Section 33.0112 a written
3 statement prohibiting the department or laboratory from retaining
4 the genetic material.

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

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

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

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

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

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

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

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

26 (c) At the time a newborn child is subjected to screening
27 tests under Section 33.011, the physician attending a newborn child

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

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

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

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

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

27 SECTION 3. Subchapter B, Chapter 33, Health and Safety

1 Code, is amended by adding Section 33.017 to read as follows:

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

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

26 (c) Notwithstanding other law, reports, records, and
27 information that do not identify a child or the family of a child

1 may be released without consent if the disclosure is for:

2 (1) statistical purposes;

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

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

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

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

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

18 (B) only newborn screening specimens are
19 disclosed; and

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

22 (d) A state officer or employee, a department contractor, or
23 a department contractor's employee, officer, director, or
24 subcontractor may not be examined in a civil, criminal, special, or
25 other judicial or administrative proceeding as to the existence or
26 contents of records, reports, or information made confidential by
27 this section unless disclosure is authorized by this section.

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

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

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

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

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

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

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

26 SECTION 6. As soon as practicable after the effective date
27 of this Act, the Department of State Health Services shall develop

1 the disclosure statement required by Section 33.0111, Health and
2 Safety Code, as added by this Act. The department shall modify an
3 existing form for use for purposes of that section.

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

ADOPTED

MAY 15 2009

Atay Saw
Secretary of the Senate

By: *Demell*

H.B. No. 1672

Substitute the following for H.B. No. 1672:

By: *Demell*

C.S. H.B. No. 1672

A BILL TO BE ENTITLED

1 AN ACT

2 relating to newborn screening.

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

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

6 Sec. 33.0021. SICKLE-CELL TRAIT. Notwithstanding any
7 provision of this chapter, the department shall include sickle-cell
8 trait in the detection and treatment program established under this
9 chapter, in the screening for heritable diseases conducted under
10 Subchapter B, and in the newborn screening services provided under
11 Subchapter C.

12 SECTION 2. Subchapter B, Chapter 33, Health and Safety
13 Code, is amended by adding Sections 33.0111 and 33.0112 to read as
14 follows:

15 Sec. 33.0111. DISCLOSURE. (a) The department shall
16 develop a disclosure statement that clearly discloses to the
17 parent, managing conservator, or guardian of a newborn child
18 subjected to screening tests under Section 33.011:

19 (1) that the department or a laboratory established or
20 approved by the department under Section 33.016 may retain for use
21 by the department or laboratory genetic material used to conduct
22 the newborn screening tests and discloses how the material is
23 managed and used; and

24 (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.

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 81ST LEGISLATIVE REGULAR SESSION

May 15, 2009

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

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

IN RE: HB1672 by Crossover (Relating to newborn screening.), **As Passed 2nd House**

No significant fiscal implication to the State is anticipated.

The bill would add sickle cell trait to the newborn screening program. The bill would define any report, record, and information relating to newborn screening as confidential and not subject to subpoena or disclosure, except as provided by the bill. The records may be disclosed for purposes of diagnosis, a court order, a medical examiner conducting an autopsy on a child, and for certain public health research purposes under certain circumstances. Reports, records and information that does not identify the child or the family of the child may be released without consent for statistical purposes, quality assurance testing, and research purposes.

The bill would require a disclosure statement to be developed by the Department of State Health Services (DSHS). The disclosure statement would inform the parent, managing conservator, or guardian that they may limit the use of genetic material by providing a written statement prohibiting the department or laboratory from retaining the genetic material or using it for other purposes. DSHS or an approved laboratory would still conduct the newborn screening test.

The bill would require a committee of legislative members to study newborn screening and submit a report no later than December 15, 2010 to both houses of the legislature.

The bill would take effect immediately upon a two-thirds vote of each house; if it does not receive the vote necessary for immediate effect, the bill would take effect September 1, 2009.

The additional testing would not be a new cost to the agency because the current screening identifies sickle cell trait. It is assumed that new procedures identified in the bill and the study of newborn screening can 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, SD, CL, BM, MB

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 81ST LEGISLATIVE REGULAR SESSION

May 10, 2009

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

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

IN RE: HB1672 by Crowover (Relating to newborn screening.), **Committee Report 2nd House, Substituted**

No significant fiscal implication to the State is anticipated.

The bill would add sickle cell trait to the newborn screening program. The bill would define any report, record, and information relating to newborn screening as confidential and not subject to subpoena or disclosure, except as provided by the bill. The records may be disclosed for purposes of diagnosis, a court order, a medical examiner conducting an autopsy on a child, and for certain public health research purposes under certain circumstances. Reports, records and information that does not identify the child or the family of the child may be released without consent for statistical purposes, quality assurance testing, and research purposes.

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The bill would require a committee of legislative members to study newborn screening and submit a report no later than December 15, 2010 to both houses of the legislature.

The bill would take effect immediately upon a two-thirds vote of each house; if it does not receive the vote necessary for immediate effect, the bill would take effect September 1, 2009.

The additional testing would not be a new cost to the agency because the current screening identifies sickle cell trait. It is assumed that new procedures identified in the bill and the study of newborn screening can 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, BM, MB

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 81ST LEGISLATIVE REGULAR SESSION

May 4, 2009

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

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

IN RE: HB1672 by Crossover (Relating to newborn screening.), **As Engrossed**

No significant fiscal implication to the State is anticipated.

The bill would add sickle cell trait to the newborn screening program. The bill would define any report, record, and information relating to newborn screening as confidential and not subject to subpoena or disclosure, except as provided by the bill. The records may be disclosed for purposes of diagnosis, a court order, a medical examiner conducting an autopsy on a child, and for certain public health research purposes under certain circumstances. Reports, records and information that does not identify the child or the family of the child may be released without consent for statistical purposes, quality assurance testing, and research purposes.

The bill would require a disclosure statement to be developed by the Department of State Health Services (DSHS). The disclosure statement would inform the parent, managing conservator, or guardian that they may limit the use of genetic material by providing a written statement prohibiting the department or laboratory from retaining the genetic material. DSHS or an approved laboratory would still conduct the newborn screening test.

The bill would require a committee of legislative members to study newborn screening and submit a report no later than December 15, 2010 to both houses of the legislature.

The bill would take effect immediately upon a two-thirds vote of each house; if it does not receive the vote necessary for immediate effect, the bill would take effect September 1, 2009.

The additional testing would not be a new cost to the agency because the current screening identifies sickle cell trait. It is assumed that new procedures identified in the bill and the study of newborn screening can 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, BM, MB

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 81ST LEGISLATIVE REGULAR SESSION

March 20, 2009

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

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

IN RE: HB1672 by Crowover (Relating to newborn screening information.), **Committee Report**
1st House, Substituted

No significant fiscal implication to the State is anticipated.

The bill would define any report, record, and information relating to newborn screening as confidential and not subject to subpoena or disclosure, except as provided by the bill. The records may be disclosed for purposes of diagnosis, a court order, a medical examiner conducting an autopsy on a child, and for certain public health research purposes under certain circumstances. Reports, records and information that do not identify the child or the family of the child may be released without consent for statistical purposes, quality assurance testing, and research purposes.

The bill would require a disclosure statement to be developed by the Department of State Health Services (DSHS). The disclosure statement would inform the parent, managing conservator, or guardian that they may limit the use of genetic material by providing a written statement prohibiting the department or laboratory from retaining the genetic material. DSHS or an approved laboratory would still conduct the newborn screening test.

The bill would take effect immediately upon a two-thirds vote of each house; if it does not receive the vote necessary for immediate effect, the bill would take effect September 1, 2009.

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, BM, MB

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 81ST LEGISLATIVE REGULAR SESSION

March 9, 2009

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

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

IN RE: HB1672 by Crowover (Relating to the confidentiality of newborn screening information.),
As Introduced

No fiscal implication to the State is anticipated.

This bill would define any report, record, and information relating to newborn screening as confidential and not subject to subpoena or disclosure, except as provided by the bill. The records may be disclosed for purposes of diagnosis, a court order, a medical examiner conducting an autopsy on a child, and for certain public health research purposes under certain circumstances. Reports, records and information that does not identify the child or the family of the child may be released without consent for statistical purposes, quality assurance testing, and research purposes.

The bill would take effect immediately upon a two-thirds vote of each house; if it does not receive the vote necessary for immediate effect, the bill would take effect September 1, 2009.

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, BM, MB

