

## **BILL ANALYSIS**

C.S.H.B. 740  
By: Crownover  
Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Several years ago, the legislature expanded the scope of newborn screening in Texas to protect the health and welfare of Texas newborns. According to interested parties, the legislation passed at that time was designed to give the Department of State Health Services (DSHS) the flexibility to update the list of disorders for which Texas provides newborn screening as technology improves and the need for additional testing becomes more apparent, noting that DSHS was able to add Severe Combined Immunodeficiency Disorder, or SCID, to the list of disorders in 2012 without the need for additional legislation.

These parties contend that, while critical congenital heart disease (CCHD) was recently added to the Recommended Uniform Screening Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, screening for CCHD involves a type of screening best performed at the hospital or birthing facility where the newborn is delivered. The parties further contend that current law does not adequately give DSHS the authority to mandate testing for disorders if that testing occurs outside the department's laboratory. C.S.H.B. 740 seeks to ensure that DSHS has the flexibility and authority needed to add new disorders to newborn screening requirements in Texas.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

### **ANALYSIS**

Section 531.0055, Government Code, as amended by Chapter 198 (C.S.H.B. 2292), Acts of the 78th Legislature, Regular Session, 2003, expressly grants to the executive commissioner of the Health and Human Services Commission all rulemaking authority for the operation of and provision of services by the health and human services agencies. Similarly, Sections 1.16-1.29, Chapter 198 (H.B. 2292), Acts of the 78th Legislature, Regular Session, 2003, provide for the transfer of a power, duty, function, program, or activity from a health and human services agency abolished by that act to the corresponding legacy agency. To the extent practical, this bill analysis is written to reflect any transfer of rulemaking authority and to update references as necessary to an agency's authority with respect to a particular health and human services program.

C.S.H.B. 740 amends the Health and Safety Code to specify that the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician is required to cause the child to be subjected to certain newborn screening tests approved by the Department of State Health Services (DSHS), rather than to subject the child to such screening tests. The bill requires DSHS to require newborn screening tests to screen for disorders listed as core and secondary conditions in the December 2011 Recommended Uniform Screening Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, rather than for disorders listed in the core panel and in the secondary targets of the

uniform newborn screening panel recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System." The bill specifies that the Newborn Screening Advisory Committee is required to advise DSHS regarding strategic planning, policy, rules, and services related to newborn screening and additional newborn screening tests for each disorder included in the panel or in another report determined by DSHS to provide more stringent newborn screening guidelines.

C.S.H.B. 740 requires DSHS, with the advice of the Newborn Screening Advisory Committee, to authorize a newborn screening test for critical congenital heart disease to be performed at a birthing facility that provides care to newborn patients and that complies with the test procedures and the standards of accuracy and precision required by DSHS for each screening test. The bill requires a birthing facility, if DSHS authorizes the performance at a birthing facility of a screening test for critical congenital heart disease, to perform the screening test on each newborn who is a patient of the facility before the newborn is discharged from the facility unless the parent declines the screening, the newborn is transferred to another facility before the screening test is performed, the screening test has previously been completed, or the newborn is discharged from the birthing facility not more than 10 hours after birth and a referral for the newborn was made to another birthing facility, physician, or health care provider. The bill requires DSHS, before requiring any additional screening test for critical congenital heart disease, to review the necessity of the additional screening test, including an assessment of the test implementation costs to DSHS, birthing facilities, and other health care providers.

C.S.H.B. 740 specifies that statutory provisions relating to a disclosure statement and consent form regarding the use and retention of genetic material used to conduct the newborn screening tests do not prohibit a physician attending a newborn child from delegating the physician's responsibilities to any qualified and properly trained person acting under the physician's supervision. The bill includes a birthing facility among the individuals and entities required to report to DSHS a confirmed case of a disorder for which a screening test is required that has been detected by a mechanism other than identification through a screening of a specimen by the department's diagnostic laboratory.

C.S.H.B. 740 includes as required members of the Newborn Screening Advisory Committee at least four physicians licensed to practice medicine in this state, including at least two physicians specializing in neonatal-perinatal medicine. The bill increases from one to two the minimum number of committee members required to be hospital representatives and sets at two the minimum number of committee members required to be persons who have family members affected by a condition for which newborn screening is or may be required and sets at two the minimum number of committee members required to be health care providers who are involved in the delivery of newborn screening services, follow-up, or treatment in this state. The bill requires the advisory committee to review the necessity of requiring additional screening tests, including an assessment of the test implementation costs to DSHS, birthing facilities, and other health care providers.

C.S.H.B. 740 requires DSHS to implement the changes made by the bill's provisions relating to the newborn screening program and requires the commissioner of state health services to appoint the additional members to the advisory committee as soon as practicable after the bill's effective date.

C.S.H.B. 740 repeals Section 33.0111(g), Health and Safety Code.

#### **EFFECTIVE DATE**

September 1, 2013.

## COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 740 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and highlighted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

### INTRODUCED

SECTION 1. Section 33.001, Health and Safety Code, is amended by amending Subdivision (1) and adding Subdivision (1-a) to read as follows:

(1) "Congenital heart defect" means an abnormality in the structure and function of the heart that exists at birth.

(1-a) "Heritable disease" means an inherited disease that may result in mental or physical retardation or death.

SECTION 2. Section 33.011, Health and Safety Code, is amended by amending Subsections (a-1) and (c) and adding Subsection (d) to read as follows:

(a-1) Except as provided by this subsection and to the extent funding is available for the screening, the department shall require newborn screening tests to screen for disorders listed as core and secondary

### HOUSE COMMITTEE SUBSTITUTE

SECTION 1. Section 33.001, Health and Safety Code, is amended by amending Subdivision (1) and adding Subdivisions (1-a) and (1-b) to read as follows:

(1) "Birthing facility" means an inpatient or ambulatory health care facility that offers obstetrical or newborn care services. The term includes:

(A) a hospital licensed under Chapter 241 that offers obstetrical services;

(B) a birthing center licensed under Chapter 244;

(C) a children's hospital; or

(D) a facility that provides obstetrical services and is maintained and operated by this state or an agency of this state.

(1-a) "Critical congenital heart disease" means an abnormality in the structure or function of the heart that exists at birth, causes severe, life-threatening symptoms, and requires medical intervention within the first few hours, days, or months of life.

(1-b) "Heritable disease" means an inherited disease that may result in mental or physical retardation or death.

SECTION 2. Section 33.011, Health and Safety Code, is amended by amending Subsections (a), (a-1), and (c) and adding Subsections (d), (e), and (f) to read as follows:

(a) The physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall cause the child to be subjected [subject the child] to screening tests approved by the department for phenylketonuria, other heritable diseases, hypothyroidism, and other disorders for which screening is required by the department.

(a-1) Except as provided by this subsection and to the extent funding is available for the screening, the department shall require newborn screening tests to screen for disorders listed as core and secondary

conditions in the December 2011 Recommended Uniform Screening Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children [~~core panel and in the secondary targets of the uniform newborn screening panel recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System"~~] or other recommendation [~~another report~~] determined by the department to provide more stringent newborn screening guidelines to protect the health and welfare of this state's newborns. The department, with the advice of the Newborn Screening Advisory Committee, may require additional newborn screening tests under this subsection to screen for other disorders or conditions. The department may exclude from the newborn screening tests required under this subsection screenings for galactose epimerase and galactokinase.

(c) Except as provided by Subsection (d), the [~~The~~] screening tests required by this section must be performed by the laboratory established by the department or by a laboratory approved by the department under Section 33.016.

(d) The department may authorize a screening test, including a screening for congenital heart defects, to be performed at a health care facility that provides newborn infant care and that complies with the test procedures and the standards of accuracy and precision required by the department for each screening test.

conditions in the December 2011 Recommended Uniform Screening Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children [~~core panel and in the secondary targets of the uniform newborn screening panel recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System"~~] or another report determined by the department to provide more stringent newborn screening guidelines to protect the health and welfare of this state's newborns. The department, with the advice of the Newborn Screening Advisory Committee, may require additional newborn screening tests under this subsection to screen for other disorders or conditions. The department may exclude from the newborn screening tests required under this subsection screenings for galactose epimerase and galactokinase.

(c) Except as provided by Subsection (d), the [~~The~~] screening tests required by this section must be performed by the laboratory established by the department or by a laboratory approved by the department under Section 33.016.

(d) The department, with the advice of the Newborn Screening Advisory Committee, shall authorize a screening test for critical congenital heart disease to be performed at a birthing facility that provides care to newborn patients and that complies with the test procedures and the standards of accuracy and precision required by the department for each screening test.

(e) If the department under Subsection (d) authorizes the performance at a birthing facility of a screening test for critical congenital heart disease, a birthing facility must perform the screening test on each newborn who is a patient of the facility before the newborn is discharged from the facility unless:

(1) the parent declines the screening;

(2) the newborn is transferred to another facility before the screening test is performed;

(3) the screening test has previously been completed; or

(4) the newborn is discharged from the birthing facility not more than 10 hours after birth and a referral for the newborn was

made to another birthing facility, physician, or health care provider.

(f) Before requiring any additional screening test for critical congenital heart disease, the department must review the necessity of the additional screening test, including an assessment of the test implementation costs to the department, birthing facilities, and other health care providers.

SECTION 3. Sections 33.0111(a), (b), and (f), Health and Safety Code, are amended 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, any health care facility authorized to perform the tests, or a laboratory established or approved by the department under Section 33.016 may retain for use by the department, health care facility, 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 33.018 [~~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 33.018(c-1) [~~33.017(e-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 33.018 [~~33.017~~].

(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 in a format that allows a parent, managing conservator, or guardian of a newborn child to consent to disclosure under Section 33.018(c-1) [~~33.017(e-1)~~];

(2) include instructions on how to complete the portions of the form described by Subdivision (1);

SECTION 3. Section 33.0111, Health and Safety Code, is amended by amending Subsections (a), (b), and (f) and adding Subsection (h) 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 33.018 [~~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 33.018(c-1) [~~33.017(e-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 33.018 [~~33.017~~].

(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 in a format that allows a parent, managing conservator, or guardian of a newborn child to consent to disclosure under Section 33.018(c-1) [~~33.017(e-1)~~];

(2) include instructions on how to complete the portions of the form described by Subdivision (1);

- (3) include the department's mailing address; and
- (4) describe how a parent, managing conservator, or guardian of a newborn child may obtain information regarding consent through alternative sources.
- (f) This section does not supersede the requirements imposed by Section 33.018 [33.017].

- (3) include the department's mailing address; and
- (4) describe how a parent, managing conservator, or guardian of a newborn child may obtain information regarding consent through alternative sources.
- (f) This section does not supersede the requirements imposed by Section 33.018 [33.017].

(h) Nothing in this section prohibits a physician attending a newborn child from delegating the physician's responsibilities under this section to any qualified and properly trained person acting under the physician's supervision.

SECTION 4. Section 33.014(a), Health and Safety Code, is amended to read as follows:

(a) If, because of an analysis of a specimen submitted under Section 33.011, the department reasonably suspects that a newborn child may have phenylketonuria, another heritable disease, hypothyroidism, or another disorder for which the screening tests are required, the department shall notify the person who submits the specimen that the results are abnormal and provide the test results to that person. The department may notify one or more of the following that the results of the analysis or of a screening test reported to the department under Section 33.015 are abnormal and recommend further testing when necessary:

- (1) the physician attending the newborn child or the physician's designee;
- (2) the person attending the delivery of the newborn child that was not attended by a physician;
- (3) the parents of the newborn child;
- (4) the health authority of the jurisdiction in which the newborn child was born or in which the child resides, if known; or
- (5) physicians who are cooperating pediatric specialists for the program.

**No equivalent provision.**

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SECTION 4. Section 33.015(a), Health and Safety Code, is amended to read as follows:

(a) Each physician, health authority, birthing facility, or other individual who has the information of a confirmed case of a disorder for which a screening test is required that has been detected by a mechanism other than identification through

a screening of a specimen by the department's diagnostic laboratory shall report the confirmed case to the department.

SECTION 5. Section 33.017(c), Health and Safety Code, is amended to read as follows:

SECTION 5. Sections 33.017(b) and (c), Health and Safety Code, are amended to read as follows:

(b) The advisory committee consists of members appointed by the commissioner of state health services. The advisory committee must include the following members:

(1) at least four physicians licensed to practice medicine in this state, including at least two physicians specializing in neonatal-perinatal medicine [health care providers];

(2) at least two [a] hospital representatives [representative];

(3) at least two persons who have family members affected by a condition for which newborn screening is or may be required under this subchapter; and

(4) at least two health care providers [persons] who are involved in the delivery of newborn screening services, follow-up, or treatment in this state.

(c) The advisory committee shall advise the department regarding strategic planning, policy, rules, and services related to newborn screening and additional newborn screening tests for each disorder included in the list described by Section 33.011(a-1).

(c) The advisory committee shall:

(1) advise the department regarding strategic planning, policy, rules, and services related to newborn screening and additional newborn screening tests for each disorder included in the list described by Section 33.011(a-1); and

(2) review the necessity of requiring additional screening tests, including an assessment of the test implementation costs to the department, birthing facilities, and other health care providers.

SECTION 6. Section 33.0111(g), Health and Safety Code, is repealed.

SECTION 6. Same as introduced version.

SECTION 7. As soon as practicable after the effective date of this Act, the Department of State Health Services shall implement the changes in law made by this Act to the newborn screening program under Chapter 33, Health and Safety Code.

SECTION 7. Same as introduced version.

No equivalent provision.

SECTION 8. (a) The change in law made

by this Act in amending Section 33.017, Health and Safety Code, regarding the qualifications of members of the Newborn Screening Advisory Committee does not affect the entitlement of a member serving on the committee immediately before the effective date of this Act to continue to serve as a member of the committee for the remainder of the member's term. The change in law applies only to a member appointed on or after the effective date of this Act.

(b) As soon as practicable after the effective date of this Act, the commissioner of state health services shall appoint the additional committee members required by Section 33.017, Health and Safety Code, as amended by this Act.

SECTION 8. This Act takes effect September 1, 2013.

SECTION 9. Same as introduced version.