SUBJECT: Newborn screening for critical congenital heart disease and other disorders

COMMITTEE: Public Health — committee substitute recommended

VOTE: 8 ayes — Kolkhorst, Naishtat, S. Davis, Guerra, S. King, Laubenberg, J.D. Sheffield, Zedler

0 nays

3 absent — Coleman, Collier, Cortez

WITNESSES: For — Charleta Guillory, March of Dimes; Carrie Kroll, Texas Hospital Association; Vi Nguyen-Kennedy, Bless Her Heart; Curtis Popp, American Heart Association; Michael Speer, Texas Medical Association and Texas Pediatric Society; Tracy Sievers; Carl Wolford; (*Registered, but did not testify:* Marisa Finley, Scott & White Center for Healthcare Policy; Eileen Garcia, Texans Care for Children; Rebekah Schroeder, Texas Children's Hospital; Bryan Sperry, Children's Hospital Association of Texas)

Against — Jeremy Blosser; Read King; (*Registered, but did not testify:* Chris Howe)

On — Jann Melton-Kissel, Department of State Health Services

BACKGROUND: Health and Safety Code, sec. 33.011(a-1) requires newborn children be screened for the inherited diseases based on guidelines in either the 2005 American College of Medical Genetics report, "Newborn Screening: Toward a Uniform Screening Panel and System" or in another report with more stringent guidelines. DSHS may also add screenings with the advice of the Newborn Screening Advisory Committee (NSAC).

Sec. 33.017 establishes the NSAC, defines its membership, and charges it with advising DSHS regarding newborn screening policy and additional newborn screening tests.

With the exception of Health and Safety Code, ch. 47, which requires newborn hearing screenings to be conducted at the "point of care" — the birthing facility itself — sec. 33.011(c) requires that screening tests be

performed at DSHS-approved laboratories. In practice, this involves drawing a blood sample from the newborn and sending it to a lab for processing.

Critical congenital heart disease (CCHD) is a congenital heart defect that causes life-threatening symptoms during the first year of life. Screening for CCHD typically occurs in the birthing facility before discharge and involves measuring a newborn's blood oxygen level with a pulse oximeter. CCHD was added to the U.S. Department of Health and Human Services' Recommended Uniform Screening Panel for newborns in 2011.

DIGEST:

CSHB 740 would require newborn screenings for CCHD, update the guidelines for required newborn screenings, authorize physicians to delegate the responsibility for screening tests, and modify the NSAC.

Critical Congenital Heart Disease. CSHB 740 would require that a screening test for CCHD be performed on each newborn in a birthing facility. CCHD testing would be required unless the test had already been performed, the parent declined the screening, the newborn was transferred to another facility before the screening test was performed, or the newborn was discharged within 10 hours with a referral to another birthing facility or health care provider.

The bill would define "birthing facility" to mean any health care facility that offered obstetrical or newborn-care services, including hospitals, birthing centers, and state-operated facilities providing obstetrical services.

DSHS would incorporate advice from the NSAC when authorizing the CCHD screening test. Before requiring any additional CCHD screening tests, DSHS would be required to assess their necessity and costs and to consider NSAC's recommendations on these matters.

Required screenings. CSHB 740 would update the standard for determining which conditions to include in the newborn screening program. The bill would replace the 2005 report by the American College of Medical Genetics with the 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."

A physician attending a delivery no longer would be personally required

to administer mandatory screening tests to each newborn child, so long as he or she ensured a properly trained person under the physician's supervision administered the tests.

Newborn Screening Advisory Committee. CSHB 740 would amend the NSAC's composition by:

- requiring the membership of at least four licensed physicians, including at least two who specialize in neonatal-perinatal medicine;
- increasing to two the number of hospital representatives;
- requiring the membership of two or more persons who have family members affected by a relevant condition; and
- specifying that the two committee members involved in newborn screening, follow-up, or treatment would have to be health-care providers.

Effective date. The bill would take effect September 1, 2013. As soon as practicable following this date, DSHS would implement the bill's changes to the newborn screening program, and the DSHS commissioner would appoint the additional committee members to the NSAC. Members serving on the committee immediately prior to the effective date would not be subject to the bill's requirements and would serve the remainder of their terms.

SUPPORTERS SAY:

CSHB 740 would improve health outcomes for newborn children, reduce health costs, and improve the functioning of the newborn screening program.

Requiring CCHD testing for all newborns would reduce preventable infant death and injury. CCHD is a leading cause of infant death, and its life-threatening symptoms affect more than 550 Texas babies a year. Even when not fatal, it can result in lifelong disabilities. Screening for CCHD with a pulse oximeter is reliable and can be done as soon as 24 hours after birth. Because medical intervention, such as surgery, is required within the first few hours, days, or months of life, requiring CCHD screening tests at the birthing facility would increase detection and treatment of this disease. Parents opposed to the test would be able to decline it.

Requiring CCHD testing would reduce long-term health care costs. Infants who survive CCHD but sustain severe injuries require elevated levels of

health care during their lives. For example, the Centers for Disease Control and Prevention (CDC) estimates the lifetime cost of a child with an intellectual disability, a possible consequence of CCHD, is $1 million per child. In comparison, a single pulse oximetry test costs between $3 and $15, and likely would be included in most insurance plans' bundled costs for postnatal care. According to the Legislative Budget Board's fiscal note, the provisions of CSHB 740 would result in no significant impact to state or local authorities, even in the short term.

CSHB 740's administrative modifications would improve the newborn screening program's functioning and effectiveness. By more clearly defining the NSAC's makeup and increasing its provider qualifications, the bill would ensure the newborn screening program's stakeholders were represented and that its recommendations were informed and reliable.

Clarifying that physicians could delegate the program's screening tests to those under their authority would align Texas statute with current physician practice and would reduce uncertainty and increase birthing facilities' flexibility in carrying out the required screenings. Statutorily updating the benchmark for required screenings would align Texas statute with current DSHS practice and medical science and signal the Legislature's intent that the newborn screening program stay current with medical and technological developments.

OPPONENTS SAY:

CSHB 740 would be an unwarranted and costly expansion of the government's authority. Although parents in theory would be able to opt-out of the CCHD screening, it is unclear whether in practice the test's opt-out provision would be understood by parents. In effect, the bill would act as a mandate that imposed the government's medical decisions on families.

CSHB 740 would increase health care costs for an unnecessary test. The CDC estimates that nationwide about only 300 infants are discharged from newborn nurseries each year with undetected CCHD, yet even a relatively inexpensive test would result in millions of additional dollars spent annually on screening. This cost would have to be paid through Medicaid, private insurance, or as an out-of-pocket expense. Although DSHS and the NSAC would be required to assess the costs of additional screening tests, there is no requirement that would make cost a limiting or even deciding factor in future screening mandates.

OTHER OPPONENTS SAY:

CSHB 740 would not adequately protect Texas newborns from inherited diseases.

The bill should be amended to include the provision in HB 740 as filed generally allowing DSHS to authorize newborn screening tests at the point of care. CSHB 740 would make CCHD screening in a birthing facility the only exception to the newborn screening program's requirement that all screenings be conducted in a DSHS-approved laboratory. This would continue to limit DSHS' flexibility to add new point-of-care screenings as they became available in the future. Requiring legislative approval for each future point-of-care test could delay or even prevent newborns from receiving warranted screenings.

CSHB 740 also would limit the number of infants who receive CCHD screening by exempting home births and allowing parents to opt-out of the screening for non-religious reasons, something the newborn screening program does not permit otherwise.

NOTES:

Unlike HB 740 as filed, the committee substitute would:

- replace "congenital heart defect" with "critical congenital heart disease," one of its subgroups;
- require CCHD screening for all newborns at birthing facilities, and provide certain exemptions from CCHD screening requirements;
- change the makeup of the NSAC and add procedural clarification for its implementation;
- allow physicians to delegate newborn screening tasks;
- require DSHS and the NSAC to review the necessity, including cost, of additional screenings; and
- define and use throughout the bill the term "birthing facility."

HB 740 as introduced would have allowed DSHS to authorize screening tests at health care facilities that provide newborn care in addition to at the laboratory.