The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Banking and Insurance

BILL:	CS/SB 124
INTRODUCER:	Health Policy Committee; Senators Ring and Clemens
SUBJECT:	Newborn Screening for Critical Congenital Heart Disease
DATE:	February 28, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	McElheney	Stovall	HP	**Fav/CS**
2.	Johnson	Burgess	BI	**Pre-meeting**
3.			AHS	
4.			AP	
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

CS/SB 124 requires the Department of Health (DOH) to adopt and enforce rules that require hospitals, ambulatory surgical centers, and birthing centers to screen newborns for critical congenital heart disease (CCHD) within the first 24 hours of life or before the newborn is discharged.

This bill amends section 383.14 of the Florida Statutes.

II. Present Situation:

Congenital Heart Disease

Congenital Heart Disease (CHD) is a term that embraces a variety of defects that are present in the structure of the heart at birth. Defects may involve the interior walls of the heart, valves inside the heart, or the arteries and veins that carry blood to the heart or out to the body. These congenital defects change the normal flow of blood through the heart, leading to a range of conditions and symptoms. CHD affects about 7 to 9 of every 1,000 live births in the United States and Europe and is the most common cause of death in the first year of life, with defects

accounting for 3 percent of all infant deaths and more than 40 percent of all deaths due to congenital malformations.[1]

Critical CHD (CCHD) is a subset of congenital heart defects that causes severe and life-threatening symptoms and requires intervention within the first days or first year of life. Critical Congenital *Cyanotic* Heart Disease is a group of congenital heart defects characterized by a diminished availability of oxygen to the body tissues.

Current methods for detecting CHD generally include prenatal ultrasound screening and careful and repeated clinical examinations, both in the hospital nursery and as part of routine well-child care. CCHD and Critical Congenital Cyanotic Heart Disease are often missed by hospital discharge and post-discharge clinical exams of infants.

Pulse oximetry screening can identify some newborns with CCHD. A pulse oximeter is a medical device that measures the percentage of hemoglobin in the blood that is saturated with oxygen. The device indirectly monitors the oxygen saturation of a patient's blood without the need to take a blood sample. It is estimated that one quarter of congenital heart defects could be detected and potentially treated by measuring blood oxygen saturation.[2] Neonates with abnormal pulse oximetry screening results need confirmatory testing for the cause of the low oxygen saturation, and immediate intervention, often involving a surgical procedure.

A screen is considered positive if: any oxygen saturation measure is less than 90 percent (in the initial screen or in repeat screens); oxygen saturation is less than 95 percent in the right hand and foot on three measures, each separated by 1 hour; or a greater than 3 percent absolute difference exists in oxygen saturation between the right hand and foot on three measures, each separated by one hour. Any screening that is greater than or equal to 95 percent in the right hand or foot with a less than or equal to 3 percent absolute difference in oxygen saturation between the right hand or foot is considered a negative screen and screening would end.[3]

Any infant with a positive screen should have a diagnostic echocardiogram. The infant's pediatrician should be notified immediately and the infant might need to be seen by a cardiologist for follow-up.[4]

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[1] Letter dated October 15, 2010, to The Honorable Kathleen Sebelius, Secretary of Health and Human Services, from R. Rodney Howell, M.D., Chairperson of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. Found at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/criticalcongenital.pdf> (Last visited on January 25, 2013).

[2] Letter dated September 21, 2011, to R. Rodney Howell, M.D., Chairperson of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, from The Honorable Kathleen Sebelius, Secretary of Health and Human Services. Found at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/cyanoticheartsecre09212011.pdf> (Last visited on January 25, 2013).

[3] *Pulse Oximetry Screening for Critical Congenital Heart Defects*, Centers for Disease Control and Prevention. Found at: <http://www.cdc.gov/ncbddd/pediatricgenetics/pulse.html> (Last visited on January 25, 2013).

[4] *Id.*

Newborn Screening

All babies born in the United States are examined for certain medical conditions soon after birth. This is called newborn screening. Over 4 million infants are screened each year. Newborn screening identifies conditions that can affect a child's long-term health or survival. Early detection, diagnosis, and intervention can prevent death or disability and enable children to reach their full potential. All babies are screened, even if they look healthy, because some medical conditions cannot be seen by just looking at the baby. Each state runs its own newborn screening program.

Newborn screening usually takes place before a newborn leaves the hospital. Most tests use a few drops of blood from pricking the baby's heel. The blood specimen is placed on a special filter paper and, in Florida, the specimen card is sent to the DOH Newborn Screening Laboratory in Jacksonville for testing. The laboratory receives about 250,000 specimens annually from babies born in Florida. The majority of the test results are reported within 24-48 hours. The DOH Children's Medical Services program provides the follow-up for all abnormal screening results.

Section 383.14, F.S., requires the Florida DOH to promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the department.

Section 383.145, F.S., establishes the state's newborn and infant hearing screening program. Hospitals perform the hearing screening on all babies prior to discharge. Licensed birth centers are required to provide referrals for the hearing screening. A hearing test involves placing a tiny earphone in the baby's ear and measuring his or her response to sound. If a screening test suggests a problem, the baby's doctor will follow up with further testing.

Most states screen for a standard number of conditions, but some states may screen for more conditions. Florida currently screens for 36 disorders, including hearing impairment, but does not screen for CHD.[5] The National Newborn Screening and Genetics Resource Center provides a current list of conditions included in each state's newborn screening program. As of January 6, 2013, screening for CCHD is required by law or rule and fully implemented in Indiana, Maryland, New Hampshire, New Jersey, Tennessee and West Virginia. Testing is required, but not implemented in Connecticut. In Delaware, CCHD screening is offered to select populations or by request.[6]

Adding Conditions to Required Screening

The DOH is required, after consultation with the Genetics and Newborn Screening Advisory Council, to adopt rules requiring every newborn in this state, prior to becoming 1 week of age, to be subjected to a test for phenylketonuria and, at the appropriate age, to be tested for other metabolic diseases and hereditary or congenital disorders *as the department deems necessary*.[7]

[5] *See* Department of Health Bill Analysis for CS/SB 124 – on file with the Senate Banking and Insurance Committee.
[6] National Newborn Screening Status Report, updated 01/06/13. Found at: http://genes-r-us.uthscsa.edu/sites/genes-r-us/files/nbsdisorders.pdf (Last visited on January 30, 2012).
[7] s. 383.14(2), F.S.

The purpose of the Genetics and Newborn Screening Advisory Council[8] is to advise the department about:

- Conditions for which testing should be included under the screening program and the genetics program.
- Procedures for collection and transmission of specimens and recording of results.
- Methods whereby screening programs and genetics services for children now provided or proposed to be offered in the state may be more effectively evaluated, coordinated, and consolidated.

At the national level, the Advisory Committee on Heritable Disorders in Newborns and Children advises the Secretary, U.S. Department of Health and Human Services, on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. The advisory committee recommends conditions that should be added to the Recommended Uniform Screening Panel.

On September 17, 2010, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children recommended that Critical Congenital *Cyanotic* Heart Disease be added to the Recommended Uniform Screening Panel.[9] Secretary Sebelius accepted the committee's recommendation on September 21, 2011, and CCHD screening was added to the Recommended Uniform Screening Panel as a core condition.[10] The Secretary included a broader group of congenital heart defects (Critical CHD) than what the Advisory Committee had originally recommended (Critical Congenital Cyanotic Heart Disease).

On January 20, 2012, the Florida Department of Health Genetics and Newborn Screening Advisory Council recommended working with the Cardiac Subcommittee of Children's Medical Services Advisory Council for recommendation of implementing Critical Congenital Heart Disease (CCHD) to the newborn screening panel.[11]

Hospital, Birth Center, and Home Deliveries

In 2011, there were 213,237 resident live births in Florida.[12] Of those live births, 98.3 percent occurred in hospitals. Physicians attended 87.3 percent of the hospital births.[13] Midwives attended 10.8 percent of live births in hospitals. Birth centers accounted for 1,482 births (0.695 percent of live births) and midwives attended 97.9 percent of birth center births. Physicians attended 1.95 percent of birth center births. In 2011, there were 2,124 births in an identified place other than a hospital or birth center and 58 births where the place of delivery was unknown.[14]

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[8] s. 383.14(5), F.S.
[9] Supra, fn 1.
[10] Supra, fn 2.
[11] Florida Newborn Screening Guidelines 2012; Found at: http://www.doh.state.fl.us/CMS/NewbornScreening/NewbornScreening/Guidelines.Final.05.24.2012small.pdf (Last visited on January 30, 2013)
[12] Department of Health, *2011 Florida Vital Statistics Annual Report – Live Births*. Found at: <http://www.flpublichealth.com/VSBOOK/pdf/2011/Births.pdf> (Last visited on January 30, 2013).
[13] *Id*.
[14] *Id*.

A November 2012 survey conducted by the Florida Newborn Screening Follow-up Program of birthing hospitals showed that 78 of 121 are performing pulse oximetry screening. Twenty five hospitals responded that they were not performing pulse oximetry screening; but, nine indicated that they would soon begin offering the screening. Eighteen hospitals did not respond to the survey.[15]

Hospitals are licensed and regulated under ch. 395, F.S., and part II of ch. 408, F.S. Birth centers are licensed and regulated under ss. 383.30-383.335, F.S., and part II of ch. 408, F.S. There are 23 licensed birth centers in Florida.

Health Insurance

Section 627.6416, F.S., requires individual health insurance policies, which provide coverage for a member of a family of the insured or subscriber, to include coverage for child-health supervision services. These services are covered from birth to age 16 years. The term, "child health supervision services" means physician-delivered or physician-supervised services that include, at a minimum, periodic visits including a history, a physical examination, a developmental assessment and anticipatory guidance, and appropriate immunizations and laboratory tests. These services must be provided in accordance with prevailing medical standards consistent with the Recommendations for Preventive Pediatric Health Care of the American Academy of Pediatrics. The recommendations currently include newborn metabolic and hemoglobin screening.

The same child health supervision requirements applicable to individual health insurance policies also apply to group, blanket, and franchise health insurance policies under s. 627.6579, F.S., and to health maintenance organization contracts under s. 641.31(30), F.S.

Insurance Mandates

Pursuant to s. 624.215, F.S., every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurance carrier, health care service contractor, or health maintenance organization as a component of individual or group policies, must submit to the Agency for Health Care Administration and the legislative committee having jurisdiction a report which assesses the social and financial impacts of the proposed coverage. The Senate Committee on Health Policy has not received such a report.

III. Effect of Proposed Changes:

The CS amends s. 383.14, F.S., to require the DOH to adopt and enforce rules that require hospitals, ambulatory surgical centers, and birthing centers to screen newborns for critical congenital heart disease (CCHD) within the first 24 hours of life or before the newborn is discharged. The rules will require screening for CCHD by testing for low blood-oxygen saturation using pulse oximetry or alternate peer-reviewed, evidence-based technologies on each newborn after the first 24 hours of life or before the newborn is discharged. This requirement is

[15] *See* Department of Health Bill Analysis, CS/SB 124 – on file with the Senate Banking and Insurance Committee.

added to an existing section of law pertaining to newborn screenings, which includes rulemaking authority for reporting test results and other responsibilities for the newborn screening program.

The effective date of the bill is July 1, 2013.

Other Potential Implications:

Section 383.14, F.S., gives the DOH, in consultation with the Genetics and Newborn Screening Advisory Council, the authority to, *by rule*, add to the list of disorders or diseases for which newborns must be screened. This provides a mechanism for newborn screening to be expanded as tests become available that are accepted by current medical practice and that are practical in the judgment of the department. If the department decides that infants should be tested for an additional condition, the department would need budget authority to cover the costs of conducting additional tests, however.

Does the Legislature want to include all 36 current mandatory tests in statute and amend the statute in the future to add tests as they become available? Is the need for approval of budget authority a sufficient check to keep the list of mandatory tests from growing out of control? Is the need for approval of budget authority a sufficient check to keep impractical tests from being added to the list of mandatory tests?

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The DOH currently collects a maximum hospital fee of $15 per live birth, as authorized in s. 383.14(3)(g), F.S., to cover the cost of newborn screening. No additional fee authority is provided in the bill.

B. Private Sector Impact:

Hospitals, birth centers, and ambulatory surgical centers will have additional screening and reporting requirements.

Early detection with prompt early treatment may lead to a better outcome for babies born with severe heart disease. Detection prior to hospital discharge may also prevent unexpected events such as death or an emergency health crisis in the home setting.

C. Government Sector Impact:

The DOH will need to track CCHD test results. The CCHD screening is similar to newborn hearing screening in that the birthing facility conducts the actual testing and the DOH tracks the results and provides surveillance activities for infants who fail the screening test.

The DOH will need to modify the current data system or purchase a separate system to receive and track infants who fail the testing for CCHD. The DOH estimates that an additional three contract staff will be needed. The DOH estimates its expenditures to be $205,992 in FY 2013-2014 and $155,992 in FY 2014-2015, and subsequent years.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 6, 2013:
The CS adds the requirement for the DOH to adopt and enforce rules requiring newborn screening for CCHD into an existing section of law pertaining to newborn screening requirements. The CS eliminates requirements specifying facility procedures to implement the screening.

B. Amendments:

None.