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 Health Regulation Committee

BILL: CS/SB 1052

INTRODUCER: Health Regulation Committee and Senator Ring

SUBJECT: Newborn Screening for Critical Congenital Heart Disease

DATE: January 26, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.	Burgess	Burgess	BI	**Pre-meeting**
3.			BC	
4.				
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:

The bill requires all licensed hospitals and licensed birth centers that provide maternity and newborn care to screen all newborns, prior to discharge, for Critical Congenital Heart Disease (CCHD). For a home birth, the health care provider in attendance is responsible for the screening for CCHD. A parent or legal guardian may object to the screening with a signed written objection. If the parent or legal guardian objects, the screening must not be completed.

The bill defines screening to mean measuring blood oxygen saturation using pulse oximetry to determine whether the newborn needs additional diagnostic evaluation for CCHD. The bill requires each hospital to designate a lead physician to be responsible for programmatic oversight of the screening and to ensure that appropriate referrals are completed. Each birth center must designate a licensed health care provider to provide programmatic oversight and to ensure that appropriate referrals are being completed.

The bill provides specific rulemaking authority to the Department of Health (DOH or department) and defines the powers and duties of the department for administering the screening requirements.

This bill creates section 383.146 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 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

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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 23, 2012).

[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 23, 2012).

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]

Newborn Screening

All babies born in the United States are checked 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 35 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

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[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 23, 2012).
[4] *Id.*
[5] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1052 – on file with the Senate Health Regulation Committee.

December 19, 2011, only one state (New Jersey) requires screening of all newborns for congenital heart disease, but the requirement has not yet been implemented.[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] 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 Secretary's 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 Genetics and Newborn Screening Advisory Council recommended that CHD be added to the panel of disorders screened in the Florida Newborn Screening Program.

[6] National Newborn Screening Status Report, updated 11/21/11. Found at: <http://genes-r-us.uthscsa.edu/nbsdisorders.pdf> (Last visited on January 23, 2012).
[7] s. 383.14(2), F.S.
[8] s. 383.14(5), F.S.
[9] Supra, fn 1.
[10] Supra, fn 2.

Hospital, Birth Center, and Home Deliveries

In 2010 there were 214,519 resident live births in Florida.[11] Of these births, 211,485 (98.6 percent) occurred in hospitals and physicians attended 88.5 percent of the hospital births.[12] Midwives attended 10.9 percent of live births in hospitals. Birth centers accounted for 1,377 births (0.64 percent of live births) and midwives attended 96.9 percent of birth center births. Physicians attended 2.8 percent of birth center births. In 2010, there were 1,508 births in an identified place other than a hospital or birth center and 149 births where the place of delivery was unknown.[13]

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 that provide coverage on an expense-incurred basis, which provide coverage for a member of a family of the insured or subscriber, to include, for children, coverage for child health supervision services. These services are covered from the moment of 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 are also applied 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 (Agency) and the legislative committee having jurisdiction a report which assesses the social and financial impacts of the proposed coverage.

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[11] Department of Health, *2010 Florida Vital Statistics Annual Report – Live Births*. Found at: <http://www.flpublichealth.com/VSBOOK/pdf/2010/Births.pdf> (Last visited on January 23, 2012).
[12] *Id.*
[13] *Id.*

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The Agency is responsible for Medicaid. Medicaid serves approximately 3.19 million people in Florida, with over half of those being children and adolescents 20 years of age or younger. Estimated Medicaid expenditures for FY 2011-2012 are approximately $20.3 billion.

The total number of live births paid for by Medicaid through fee for service and health maintenance organizations during FY 2010-2011 was 130,989.[14]

Under s. 383.145(3)(j), F.S., which establishes the requirements for newborn and infant hearing screening, the Medicaid program must cover the initial procedure for screening the hearing of newborns or infants and any medically necessary follow-up reevaluations leading to diagnosis. These services are reimbursable under Medicaid as an expense compensated supplemental to the per diem rate for Medicaid patients enrolled in MediPass or Medicaid patients covered by a fee for service program. For Medicaid patients who are enrolled in a health maintenance organization, Medicaid must reimburse providers directly at the Medicaid rate. These services may not be considered a covered service for the purposes of establishing the payment rate for Medicaid health maintenance organizations. Nonhospital-based providers are eligible to bill Medicaid for the professional and technical component of each procedure code.

Medicaid pays hospitals a per diem rate for hospital inpatient services based on hospital cost reports. Cost reports are submitted annually and rates are adjusted as appropriate. Standard testing of a patient’s vital signs is included in the per diem rate regardless of the Medicaid recipient’s age. Measuring blood oxygen saturation using pulse oximetry is considered a standard part of testing a patient’s vital signs. A separate screening for newborns for congenital heart disease is not currently reimbursed by Medicaid other than as a part of the hospital per diem rate. Medicaid currently does not reimburse separately for the screening of newborns for congenital heart disease in any other setting either.

III. Effect of Proposed Changes:

The bill requires each licensed hospital and birth center that provides maternity and newborn care services to screen all newborns, prior to discharge, for CCHD. This requirement must be implemented by October 1, 2012. For home births, the health care provider in attendance is responsible for the screening.

The bill defines screening to mean measuring blood oxygen saturation using pulse oximetry to determine whether the newborn needs additional diagnostic evaluation for CCHD.

A parent or legal guardian may object to the screening by providing a signed written objection, in which case the screening must not be completed. The physician, midwife, or other person who

[14] See Agency for Health Care Administration 2012 Bill Analysis and Economic Impact Statement for SB 1052 – on file with the Senate Health Regulation Committee.

is attending the newborn is required to maintain a record that the screening has not been performed and attach the written objection.

Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

The bill requires each hospital to formally designate a lead physician to be responsible for programmatic oversight of the newborn CCHD screening and to ensure that the appropriate referrals are being completed following a positive screening test result. The bill requires each birth center to designate a licensed health care provider to be responsible for programmatic oversight and to ensure that the appropriate referrals are being completed.

The DOH is provided with specific rulemaking authority. The bill requires the department to administer and provide services pursuant to this newly created section of law and specifically to:

- Furnish all physicians, county health departments, perinatal centers, birthing centers, and hospitals forms on which the results of tests for CCHD are to be reported to the department.
- Charge and collect fees sufficient to administer the newborn screening program for CCHD.

The effective date of the bill is July 1, 2012.

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.

In regard to CCHD, both the federal and state advisory groups have recommended adding CCHD to the list of mandatory newborn screening. If the Legislature provides budget authority to the department, there is no need to specifically include CCHD in the Florida Statutes. If the Legislature does not provide this budget authority, the bill cannot be implemented.

Does the Legislature want to include all thirty-four 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:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

The requirement in the bill that the objection to screening must contain the parent’s or guardian’s signature may violate the right of privacy under the Florida Constitution, Article I, Section 23.

The bill may impair existing contracts since the requirement for health insurers and health maintenance organizations to cover screening for CCHD takes effect on July 1, 2012, and does not provide an exemption for existing contracts.

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. Adding CCHD to the list of newborn screenings could require an increase in the hospital fee from $15 to $15.78 per live birth.

B. Private Sector Impact:

Hospitals, birth centers, and health care practitioners attending home births 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.

The private sector fiscal impact is indeterminate at this point.

C. Government Sector Impact:

The DOH will need to create and implement a system to track CCHD test results within the existing program structure. 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 main costs of adding CCHD to the Florida Newborn Screening Program are related to the necessary modifications of the current data system to add the screening results and staff time to track infants who fail the screening test. Follow-up actions would include communicating with physicians and parents regarding the outcome of the confirmatory testing and obtaining the final diagnosis and outcome. The department estimates its expenditures to be $166,191 in FY 2012-2013 and $154,922 in FY 2013-2014.

Funding for the program could come from surplus revenue generated from billing for other disorders tested in the Newborn Screening program. The department must be provided budget authority to spend the surplus funding for this purpose. As of November 22, 2011, the Newborn Screening program had a surplus of revenue in FY 2010-2011 totaling $2,110,778.[15]

The fiscal impact on the state group insurance plans is indeterminate at this point.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The requirement for a written signature for objecting to screening by a parent or guardian at lines 57 and 58 is more prescriptive than a similar requirement under s. 383.14(4), F.S., which does not require a signature.

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal mandating health coverage to submit to the Agency and the appropriate legislative committees having jurisdiction a report assessing the social and financial impacts of the proposed coverage. Neither the Committee on Health Regulation nor the Committee on Banking and Insurance received a report analyzing newborn screening for CCHD as created by the bill.

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 Regulation on January 25, 2012:
The CS narrows the screening requirements to apply to *Critical* Congenital Heart Disease

[15] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1052 – on file with the Senate Health Regulation Committee.

and specifies that screening means measuring blood oxygen saturation using pulse oximetry. The CS requires birth centers and the health care providers in attendance at home births to conduct the test rather than requiring them to refer the infant to a hospital or physician. The CS no longer requires a physician to conduct the screening test. The CS removes the requirement for Medicaid to pay for the screening in addition to its usual reimbursement to providers. It also removes the requirement for health insurers and health maintenance organizations to compensate providers for the screening test.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.