HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1073 Newborn Screenings
SPONSOR(S): Professions & Public Health Subcommittee, Aloupis
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	17 Y, 0 N, As CS	Morris	McElroy
2) Health Care Appropriations Subcommittee	13 Y, 0 N	Aderibigbe	Clark
3) Health & Human Services Committee	19 Y, 0 N	Morris	Calamas

SUMMARY ANALYSIS

Cytomegalovirus (CMV) is a common virus that infects people of all ages. Over half of adults are infected with CMV by age 40. Most people infected with CMV show no signs or symptoms. Pregnant women infected with CMV may pass the virus on to their baby. Approximately one of every 200 babies is born with congenital CMV. About one in five babies with congenital CMV have long-term health problems, including hearing loss. Current law requires that a newborn hearing screening must be conducted on all newborns in hospitals in this state on birth admission. Screening for congenital CMV is not required under current law.

CS/HB 1073 requires a hospital or other state-licensed birthing facility to administer a test approved by the U.S. Food and Drug Administration (FDA) on a newborn to screen for congenital CMV should the newborn fail his or her screening for hearing loss. The congenital CMV test must be administered before the newborn becomes 21 days of age or before discharge, whichever occurs earlier.

Current law requires birth centers to refer newborns to a licensed audiologist, physician, or hospital for screening for detection of hearing loss before the newborn is discharged. If the birth is a home birth, the health care provider in attendance must provide a referral to a licensed audiologist, hospital, or other newborn hearing screening provider. In instances where a home birth is not attended by a health care provider, the bill requires the newborn's primary health care provider to coordinate a referral for hearing loss screening. If the newborn fails the hearing screening, the primary care provider must refer the newborn for a FDA-approved test, or an equivalent test, for CMV.

Currently, all newborns delivered in a hospital must have a hearing screening prior to being discharged. However, if the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 30 days after birth. The bill requires screenings in these cases to be completed within 21 days after birth.

Current law requires that health care providers in attendance of a home birth to coordinate and refer newborns to a licensed audiologist, a hospital, or another newborn hearing screening provider within 30 days after birth. The bill reduces the amount of days such referral is required from 30 days after birth to 7 days after birth.

The bill requires the results of a newborn hearing screening and congenital CMV and any related diagnostic testing to be reported to DOH within 7 days after receipt of such results.

The bill has an insignificant fiscal impact on DOH which can be absorbed within existing resources and no fiscal impact on local governments.

The bill provides an effective date of January 1, 2023.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Newborn Screening Program

The Legislature created the Florida Newborn Screening Program (NSP) within the Department of Health (DOH), to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[1] The NSP also promotes the identification and screening of all newborns in this state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services.[2]

The NSP involves coordination among several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (state laboratory), DOH Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, and referral centers, birthing centers, and physicians throughout the state.[3] Health care providers in hospitals, birthing centers, perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NSP screening process.[4] This includes a risk assessment for prenatal women, and risk factor analysis and screening for postnatal women and newborns as well as laboratory screening for selected disorders in newborns.[5] The NSP attempts to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[6] While the NSP attempts to screen all prenatal women and newborns, parents and guardians may decline the screening.[7]

Health care providers perform non-laboratory NSP screening, such as hearing and risk factor analysis, and report the results to the Office of Vital Statistics. If necessary, health care providers refer patients to the appropriate health, education, and social services.[8] Health care providers in hospitals and birthing centers perform specimen collection for laboratory NSP screening by collecting a few drops of blood from the newborn's heel on a standardized specimen collection card.[9] The specimen card is then sent to the state laboratory for testing.[10] The results of the laboratory test are released to the newborn's health care provider. In the event that a newborn screen has an abnormal result, the baby's health care provider, or a nurse or specialist from NSP's Follow-up Program provides follow-up services and referrals for the child and his or her family.[11]

To administer the NSP, DOH is authorized to charge and collect a fee not to exceed $15 per live birth occurring in a hospital or birth center.[12] DOH must calculate the annual assessment for each hospital and birth center, and then quarterly generate and mail each hospital and birth center a statement of the

[1] S. 383.14(1), F.S.
[2] Id.
[3] S. 383.14, F.S.
[4] *Supra*, note 1.
[5] Id.
[6] Florida Department of Health, Florida Newborn Screening Guidelines, 2012, http://floridanewbornscreening.com/wp-content/uploads/guidelines-final-05-24-2012small-1.pdf (last visited Jan. 29, 2022).
[7] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[8] Id.
[9] Florida Newborn Screening, What is Newborn Screening?, https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited Jan. 29, 2022). *See also* Specimen Collection Card, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited Jan. 29, 2022).
[10] Id.
[11] Id.
[12] S. 383.14(3)(g)1., F.S.

amount due.[13] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[14] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[15] DOH does not bill families that do not have insurance coverage.[16]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council to advise DOH about which disorders to include in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[17] Florida's NSP currently screens for 57 conditions, 53 of which are disorders recommended by the federal Recommended Uniform Screening Panel,[18] including 35 core conditions and 22 secondary conditions.[19]

Florida does not currently screen for congenital cytomegalovirus (CMV).

Newborn and Infant Hearing Screening

Section 383.145, F.S., requires a newborn hearing screening for all newborns in hospitals before discharge. When a newborn is delivered in a facility other than a hospital, the parents must be instructed on the importance of having the hearing screening performed and must be given information to assist them in having the screening performed within three months after the child's birth.[20]

Before a newborn is discharged from a hospital or other state-licensed birthing facility, and unless objected to by the parent or legal guardian, the newborn must be screened for the detection of hearing loss to prevent the consequences of unidentified disorders. However, if the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 30 days after the birth. Before a newborn is discharged from a licensed birth center, such facility must refer the newborn to a licensed audiologist, physician, or hospital for screening for detection of hearing loss and referral for appointment must be made within 30 days after discharge. If the birth is a home birth, the health care provider in attendance must provide a referral to a licensed audiologist, hospital, or other newborn hearing screening provider and the referral for appointment must be made within 30 days after the birth.[21]

All screenings must be conducted by a licensed audiologist, a licensed physician, or appropriately supervised individual who has completed documented training specifically for newborn hearing screening. When ordered by the treating physician, screening of a newborn's hearing must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the United States Food and Drug Administration (FDA).[22]

A child who is diagnosed as having a permanent hearing impairment must be referred by the licensee or individual who conducted the screening to the primary care physician for medical management, treatment, and follow-up services. Furthermore, any child from birth to 36 months of age who is diagnosed as having a hearing impairment that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program by the licensee or individual who conducted the screening serving the geographical area in which the child resides. Any person who is

[13] Id.
[14] S. 383.14(3)(g), F.S.
[15] S. 383.14(3)(h), F.S.
[16] *Supra*, note 3.
[17] S. 383.14(5), F.S.
[18] The Recommended Uniform Screening Panel is a list of disorders that the Secretary of the U.S. Department of Health and Human Services recommends for states to screen as part of their statute universal newborn screening programs. See Health Resources & Services Administration, *Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel,* https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html (last visited Jan. 22, 2022).
[19] Florida Newborn Screening, *What is Screened*, https://floridanewbornscreening.com/conditions/core-secondary-conditions/ (last visited Jan. 22, 2022).
[20] S. 383.145(3), F.S.
[21] Id.
[22] Id

not covered through insurance and cannot afford the costs for testing must be given a list of newborn hearing screening providers who provide the necessary testing free of charge.[23]

Cytomegalovirus

Cytomegalovirus is a common virus for people of all ages; however, a healthy person's immune system usually keeps the virus from causing illness.[24] In the United States, nearly one in three children are infected with CMV by age five. Over half of adults have been infected with CMV by age 40. Once CMV is in a person's body, it stays there for life and can reactivate. A person can also be re-infected with a different strain of the virus. Most people with CMV infection have no symptoms and aren't aware that they have been infected.[25]

A pregnant woman can pass CMV to her unborn baby. The virus in the woman's blood can cross through the placenta and infect the infant. This can happen when a pregnant woman is infected with CMV for the first time or is infected with CMV again during pregnancy.[26] Some infants with congenital CMV infection have health problems that are apparent at birth or that develop later during infancy or childhood. In the most severe cases, CMV can cause the death of an unborn child (pregnancy loss).

Infants with congenital CMV infection may have signs at birth, which include:[27]

- Rash;
- Jaundice (yellowing of the skin or whites of the eyes);
- Microcephaly (small head);
- Low birth weight;
- Hepatosplenomegaly (enlarged liver and spleen);
- Seizures; and
- Retinitis (damaged eye retina).

Infants with signs of congenital CMV infection at birth may have long-term health problems, such as:[28]

- Hearing loss;
- Developmental and motor delay;
- Vision loss;
- Microcephaly (small head); and
- Seizures.

Some infants without signs of congenital CMV infection at birth may have hearing loss. Hearing loss may be present at birth or may develop later, even in infants who passed the newborn hearing test.[29]

CMV is the most common infectious cause of birth defects in the United States. About one out of 200 children are born with congenital CMV. One out of five infants with congenital CMV will have symptoms or long-term health problems, such as hearing loss. Hearing loss may progress from mild to severe during the first two years of life, which is a critical period for language learning. Over time, hearing loss can affect a child's ability to develop communication, language, and social skills.[30]

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[23] Id.
[24] About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, https://www.cdc.gov/cmv/overview.html (last visited Jan. 29, 2022).
[25] Id.
[26] Babies Born with Congenital Cytomegalovirus (CMV), Centers for Disease Control and Prevention, https://www.cdc.gov/cmv/congenital-infection.html, (last visited Jan. 29, 2022).
[27] Id.
[28] Id.
[29] Id.
[30] CMV Fact Sheet for Healthcare Providers, Centers for Disease Control and Prevention, https://www.cdc.gov/cmv/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20(CMV)%20is%20the%20most,Hearing%20loss (last visited Jan. 29, 2022).

Infants may have hearing loss that may or may not be detected by newborn hearing test. Congenital CMV infection is diagnosed by detection of CMV DNA in the urine, saliva (preferred specimens), or blood, within three weeks after birth. Infection cannot be diagnosed using tests that detect antibodies to CMV. Congenital CMV infection cannot be diagnosed using samples collected more than three weeks after birth because testing after this time cannot distinguish between congenital infection and an infection acquired during or after delivery.[31]

Infants who show signs of congenital CMV disease can be treated with medicines called antivirals. Antivirals may decrease the severity of hearing loss. Infants who get treated with antivirals should be closely monitored by their doctor because of possible side effects.[32]

Current law does not require the Newborn Screening Program, hospitals, birthing centers or health care practitioners to screen or test for congenital CMV.

Effect of the Bill

Newborn and Infant Hearing Screening

CS/HB 1073 requires a hospital or other state-licensed birthing facility to administer a FDA-approved test, or other diagnostically equivalent test, on a newborn to test for congenital cytomegalovirus should the newborn fail his or her screening for hearing loss. The congenital cytomegalovirus test must be administered before the newborn becomes 21 days of age or before discharge, whichever occurs earlier. The bill does not address whether the costs associated with the test are to be borne by the parents of the newborn, insurers or the hospital or birthing center.

Current law requires that all newborns delivered in a hospital must have a hearing screening performed prior to being discharged. However, if the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 30 days after birth. The bill requires screenings in these cases to be completed within 21 days after birth.

Current law requires that health care providers in attendance of a home birth are responsible for coordination and referral to a licensed audiologist, a hospital, or another newborn hearing screening provider within 30 days after birth. The bill requires that the referral for appointment be made within 7 days after birth. For instances in which a home birth is not attended by a health care provider, the bill specifies the newborn's primary care provider is responsible for coordinating the referral. If the newborn fails the screening, the primary care provider must refer the newborn for a FDA-approved test or other equivalent test for CMV.

The bill requires that the results of a newborn hearing screening and congenital cytomegalovirus and any related diagnostic testing to be reported to DOH within 7 days after receipt of such results.

The bill makes technical and conforming changes.

The bill provides an effective date of January 1, 2023.

B. SECTION DIRECTORY:

Section 1: Amends s. 383.145, F.S., relating to newborn and infant hearing screening.
Section 2: Provides an effective date of January 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

[31] About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, available at https://www.cdc.gov/cmv/overview.html (last visited Jan. 29, 2022).
[32] Congenital CMV and Hearing Loss, Centers for Disease Control and Prevention, available at https://www.cdc.gov/cmv/hearing-loss.html, (last visited Jan. 29, 2022).

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH estimates that four full-time equivalent (FTE) positions will be needed to implement the provisions of the bill at a cost of $372,153. Additionally, nonrecurring funds of $68,596 are needed for data system updates.

   A review of the department's vacant positions shows there are sufficient existing vacancies from which resources can be redirected to fund these new positions to implement the provisions of this legislation. These positions have been vacant for over 180 days, and the department has the ability to internally reorganize personnel as needed. Additionally, the nonrecurring system updates can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The number of infants that may be affected by this bill is unknown; however, in 2021, 9,500 infants failed the newborn hearing screening.[33] The bill would require each of these infants to undergo CMV testing. Staff estimates the costs for CMV tests to be between $45-$70 per tests. This equates to $427,500-$665,000 in testing costs.

The bill does not address whether costs associated with the administration of these tests are to be borne by the parents of the newborn, insurers, licensed health care providers, hospitals or birthing centers.

D. FISCAL COMMENTS:

None.

[33] Id.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 2, 2022, the Professions and Public Health Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Removed the requirement that a birth center ensure all newborns are referred to a licensed physician for a hearing loss screening;
- Required birth centers and the health care provider in attendance at home births to refer newborns for hearing loss screenings within 7 days after discharge; and
- Required a newborn's primary care provider to refer the newborn for a FDA-approved congenital cytomegalovirus test if the newborn was born at home or in a birth center.

This analysis is drafted to the committee substitute as passed by the Professions and Public Health Subcommittee.