

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 435 Newborn Hearing Screenings

SPONSOR(S): Melo and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 394

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Guzzo	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

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, and approximately one of every 200 babies is born with congenital CMV (CCMV). About one in five babies with CCMV have long-term health problems, including hearing loss. Current law requires hospitals to conduct a hearing screening on all newborns upon birth. Screening for congenital CMV is not required under current law.

Florida's Newborn Screening Program (NSP), operated by the Department of Health (DOH), screens all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, including hearing loss and CCMV.

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. Under current law, if a newborn fails the hearing screening, the hospital or other state-licensed birthing facility is required to administer an FDA-approved test, or other diagnostically equivalent test, on the newborn to screen for CCMV. The CCMV test must be administered before the newborn becomes 21 days of age or before discharge, whichever occurs earlier. In 2021, 8,500 newborns were tested for CCMV because they did not pass their hearing screening.

HB 435 requires hospitals and other state-licensed birthing facilities that provide maternity and newborn care services to screen all newborns for CCMV, instead of only newborns who fail hearing screenings—as required by current law. Additionally, the bill requires birth centers to refer all newborns for administration of CCMV testing within 7 days after discharge. For home births, the bill requires the healthcare provider in attendance to refer all newborns for CCMV testing within 7 days after the baby is born. The bill is expected to increase, from 8,500 to 224,000, the number of newborns tested annually for CCMV.

The bill has a significant negative fiscal impact on the Department of Health, and no fiscal impact on local government.

The bill provides an effective date of July 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 the 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 across 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 select disorders in newborns.⁵ The NSP attempts to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for select 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*. Available at <https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf> (last visited March 28, 2023).

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?* Available at <https://floridanewbornscreening.com/parents/what-is-newborn-screening/> (last visited March 28, 2023). See also, Florida Newborn Screening, *Specimen Collection Card*, <http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png> (last visited March 28, 2023).

¹⁰ *Id.*

¹¹ *Id.*

¹² S. 383.145(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 58 conditions, 55 of which are screened through the collection of blood spots. Screening of the other three conditions—hearing screening, critical congenital heart defect (CCHD) or pulse oximetry, and congenital cytomegalovirus (CCMV) targeted screening—are completed at the birthing facility through point of care (POC) testing.¹⁸

Congenital Cytomegalovirus

Cytomegalovirus (CMV) is a common virus for people of all ages; however, a healthy person's immune system usually keeps the virus from causing illness.¹⁹ 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.²⁰

CMV in a newborn is known as congenital CMV (CCMV). 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 CCMV for the first time or is infected with CCMV again during pregnancy.²¹ Some infants with CCMV infection have health problems that are apparent at birth or that develop later during infancy or childhood. In the most severe cases, CCMV can cause the death of an unborn child (pregnancy loss).

Infants with CCMV infection may have signs at birth, which include:²²

- 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).

¹³ *Id.*

¹⁴ S. 383.145(3)(g), F.S.

¹⁵ S. 383.145(3)(h), F.S.

¹⁶ *Supra*, note 3.

¹⁷ S. 383.14(5), F.S.

¹⁸ Department of Health, Agency Analysis of 2023 HB 435 (February 14, 2023).

¹⁹ About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, <https://www.cdc.gov/cmV/overview.html> (last visited March 29, 2023).

²⁰ *Id.*

²¹ Babies Born with Congenital Cytomegalovirus (CMV), Centers for Disease Control and Prevention, <https://www.cdc.gov/cmV/congenital-infection.html>, (last visited March 29, 2023).

²² *Id.*

Infants with signs of CCMV infection at birth may have long-term health problems, such as:²³

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

Some infants without signs of CCMV 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.²⁴

CCMV is the most common infectious cause of birth defects in the United States. About one out of 200 children are born with CCMV. One out of five infants with CCMV 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.²⁵

Infants may have hearing loss that may or may not be detected by newborn hearing test. CCMV infection is diagnosed by detection of CCMV DNA in the urine, saliva (preferred specimens), or blood, within three weeks after birth. Infection cannot be diagnosed using tests that detect antibodies to CCMV. CCMV 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.²⁶

Infants who show signs of CCMV 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.²⁷

CCMV and the Newborn Screening Program

Section 383.145, F.S., requires a newborn hearing screening for all newborns in hospitals before discharge.

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.²⁸ However, if the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 21 days after the birth.²⁹

In 2022, the legislature enacted a law to provide additional testing requirements for hearing loss in newborns.³⁰ Now, if a newborn fails the hearing screening, the hospital or birthing facility is required to administer an FDA-approved test, or other diagnostically equivalent test, on the newborn to screen for CCMV. The CCMV test must be administered before 21 days of age or before discharge, whichever occurs earlier.³¹

²³ Id.

²⁴ Id.

²⁵ CMV Fact Sheet for Healthcare Providers, Centers for Disease Control and Prevention, [https://www.cdc.gov/cm/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20\(CMV\)%20is%20the%20most,Hearing%20loss](https://www.cdc.gov/cm/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20(CMV)%20is%20the%20most,Hearing%20loss) (last visited March 29, 2023).

²⁶ About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cm/overview.html> (last visited March 29, 2023).

²⁷ Congenital CMV and Hearing Loss, Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cm/hearing-loss.html>, (last visited March 29, 2023).

²⁸ S. 383.145(3)(a), F.S.

²⁹ S. 383.145(3)(g), F.S.

³⁰ Ch. 2022-25, Laws of Fla.

³¹ S. 383.145(3)(a), F.S.

Before a newborn is discharged from a licensed birth center, such facility must refer the newborn to an audiologist, a hospital, or other newborn hearing screening provider, for screening for detection of hearing loss and referral for appointment must be made within 7 days after discharge. If the birth is a home birth, the health care provider in attendance must provide a referral to an audiologist, a hospital, or other newborn hearing screening provider within 7 days after the birth.³² If a newborn is born in a licensed birth center or the birth is a home birth, and the newborn fails the hearing screening, the newborn's primary care provider must refer the newborn for administration of an FDA-approved test, or other diagnostically equivalent test, on the newborn to screen for CMV.³³

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.³⁴ 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).³⁵

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.

In 2021, 8,500 newborns did not pass their hearing screenings.³⁶

Effect of the Bill

The bill expands CCMV testing to all newborns in Florida, approximately 224,000 babies annually, rather than only those who fail a hearing screening.³⁷ As a result, an additional 215,000 newborns will be tested for CCMV annually.

The bill requires hospitals and other state-licensed birthing facilities that provide maternity and newborn care services to screen all newborns for CCMV. Additionally, the bill requires birth centers to refer all newborns for CCMV testing within 7 days after discharge. For home births, the bill requires the health care provider in attendance to refer all newborns for CCMV testing within 7 days after the baby is born.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 383.145, F.S., relating to newborn and infant hearing screenings.

Section 2: Provides an effective date of July 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

³² S. 383.145(3)(d), F.S.

³³ S. 383.145(3)(e), F.S.

³⁴ S. 383.145(3)(f), F.S.

³⁵ S. 383.145(3)(i), F.S.

³⁶ *Supra* note 18.

³⁷ *Supra* note 18.

See fiscal comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Medicaid, private insurers, and families would be billed for the CCMV tests. The estimated cost for CCMV testing by urine polymerase chain reaction range from \$69 to \$346 per test. Hospitals, birthing facilities, and primary care providers could also incur the cost for additional testing supplies and equipment if they are not equipped to test for CCMV.³⁸

D. FISCAL COMMENTS:

The bill is expected to have a significant negative fiscal impact on DOH—\$1,230,850 recurring and \$1,585,050 non-recurring—for increased staffing and technology updates.

Staffing

DOH would need increased staffing to expand CCMV follow-up activities as follows:

- 1 FTE for education on collecting and reporting CCMV test results;
- 2 FTEs for specialized and expedited follow-up; and
- 2 FTEs for data entry of CCMV information.

The total cost of increased staffing is \$464,797—\$440,850 recurring and \$23,947 non-recurring.

Technology

DOH anticipates the need to transition to a statewide electronic laboratory to allow hospitals to electronically order screenings and report screening results.³⁹ DOH cannot put a timeframe on the transition.⁴⁰ DOH will request additional funding in future fiscal years to support this initiative to move from a manual to electronic process to submit newborn screening laboratory orders and receive screening results, including hearing, CCHD, and CCMV.⁴¹

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

³⁸ *Id.*

³⁹ Department of Health, Agency Analysis of 2023 HB 435, p. 6. On file with the Healthcare Regulation Subcommittee.

⁴⁰ *Id.*

⁴¹ *Id.*

The bill does not appear to create a need for rule-making or rule-making authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES