HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 499 Congenital Cytomegalovirus Screenings
SPONSOR(S): Healthcare Regulation Subcommittee, Melo
TIED BILLS: **IDEN./SIM. BILLS:** SB 168

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	18 Y, 0 N, As CS	Osborne	McElroy
2) Health Care Appropriations Subcommittee		Aderibigbe	Clark
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). Some infants with CCMV infection have health problems that are apparent at birth or that develop later during infancy or childhood. About one in five babies with CCMV have long-term health problems, including hearing loss.

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. 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.

Current law requires all newborns be screened for hearing loss at birth, unless such screening is objected to by the newborn's parent or guardian; newborns who fail the hearing screening must also be screened for CCMV. In 2021, 8,500 newborns did not pass their hearing screening, of which, 300 were diagnosed with hearing loss.

CS/HB 499 expands the population which must undergo mandatory CCMV testing beyond the current population of infants who fail the required newborn hearing screening to include infants admitted to a neonatal intensive care unit within 21 days of birth for specified reasons, and newborns who are transferred to another facility for a higher level of care.

The bill also requires that children diagnosed with a congenital cytomegalovirus infection, with or without hearing loss, be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring.

The bill has an insignificant fiscal impact on the Department of Health that can be absorbed within existing resources. The bill has no fiscal impact on local government.

The bill provides an effective date of July 1, 2024.

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] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to 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 and the results 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.[10]

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.[11] 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

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[1] S. 383.14(1), F.S.
[2] *Id.*
[3] S. 383.14, F.S.
[4] *Id.*
[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 January 26, 2024).
[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 January 26, 2024). *See also,* Florida Newborn Screening, *Specimen Collection Card*, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited January 26, 2024).
[10] *Id.*
[11] S. 383.145(3)(g)1., F.S.

amount due.[12] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[13] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[14] DOH does not bill families that do not have insurance coverage.[15]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council to advise DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[16] 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.[17]

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.[18] 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.[19]

CMV that is present in a newborn at birth is known as congenital CMV (CCMV). Congenital CMV occurs when the virus is present in a pregnant woman's blood and crosses the placenta to the fetus. This can happen if a woman is infected with CMV for the first time while she is pregnant, or is infected with CMV again during pregnancy.[20] In the most severe cases, a CMV infection can cause a woman to lose her pregnancy.

Some infants with CCMV infection have health problems that are apparent at birth or that develop later during infancy or childhood. CCMV is the most common infectious cause of birth defects in the United States; approximately one in 200 infants are born with CCMV.[21] 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).

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

- Hearing loss;

[12] *Id.*
[13] S. 383.145(3)(g), F.S.
[14] S. 383.145(3)(h), F.S.
[15] *Supra*, note 3.
[16] S. 383.14(5), F.S.
[17] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Healthcare Regulation Subcommittee.
[18] Centers for Disease Control and Prevention. *About Cytomegalovirus (CMV)*. Available at https://www.cdc.gov/cmv/overview.html (last visited January 26, 2024).
[19] *Id.*
[20] Centers for Disease Control and Prevention. *Babies Born with Congenital Cytomegalovirus (CMV)*. Available at https://www.cdc.gov/cmv/congenital-infection.html, (last visited January 26, 2024).
[21] Centers for Disease Control and Prevention. *CMV Fact Sheet for Healthcare Providers*. Available at https://www.cdc.gov/cmv/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20(CMV)%20is%20the%20most,Hearing%20loss (last visited January 26, 2024).
[22] *Supra,* note 20.
[23] *Id.*

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

One out of five infants with CCMV will have symptoms or long-term health problems, such as hearing loss. Approximately 15% of infants with CCMV will not have signs at birth, but will later develop hearing loss.[24] Infants may have hearing loss that may or may not be detected by newborn hearing test. Hearing loss may be present at birth or may develop later, even in infants who passed the newborn hearing test.[25] 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.[26]

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.[27] 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 for possible side effects.[28]

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.[29]

In 2022, the Legislature enacted a law to provide additional testing requirements for hearing loss in newborns.[30] Under current law, 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]

For births occurring in a non-hospital setting, specifically a licensed birth center or private home, the facility or attending health care provider is responsible for providing a referral to an audiologist, a hospital, or other newborn hearing screening provider within 7 days after the birth or discharge from the facility.[32] 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.[33] 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).[34]

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[24] *Supra*, note 21.
[25] *Id.*
[26] Centers for Disease Control and Prevention. *CMV Fact Sheet for Healthcare Providers*. Available at https://www.cdc.gov/cmv/fact-sheets/healthcare-providers.html#:~:text=Cytomegalovirus%20(CMV)%20is%20the%20most,Hearing%20loss (last visited January 26, 2024).
[27] Centers for Disease Control and Prevention. *About Cytomegalovirus (CMV).* Available at https://www.cdc.gov/cmv/overview.html (last visited January 26, 2024).
[28] Centers for Disease Control and Prevention. *Congenital CMV and Hearing Loss*. Available at https://www.cdc.gov/cmv/hearing-loss.html, (last visited January 26, 2024).
[29] S. 383.145(3), F.S. 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.
[30] Ch. 2022-25, Laws of Fla.
[31] S. 383.145(3)(a), F.S.
[32] S. 383.145(3)(d), F.S.
[33] S. 383.145(3)(f), F.S.
[34] S. 383.145(3)(i), F.S.

If an infant born in a licensed birth center or private home fails the hearing screening, the infant's primary care provider must refer the infant for the administration of an FDA-approved test, or other diagnostically equivalent test, on the newborn to screen for CCMV.[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.[36]

In 2021, 8,500 newborns did not pass their hearing screenings and 300 were diagnosed with hearing loss.[37]

Effect of the Bill

CS/HB 499 expands the population which must undergo mandatory CCMV testing beyond the current population of infants who fail the required newborn hearing screening to include infants admitted to a neonatal intensive care unit within 21 days of birth for any of the following reasons:

- Premature birth prior to 35 weeks gestation;
- Cardiac care; or
- Medical or postsurgical treatment with an anticipated hospital stay greater than three weeks.

The bill requires that for an infant who is transferred to another facility for a higher level of care, the receiving hospital must initiate the CCMV screening of the infant, unless the screening was already performed by the transferring hospital or birthing facility. Infants who are admitted or transferred for intensive or prolonged care must be screened for CCMV regardless of whether they have failed a hearing screening.

The bill also requires that children diagnosed with a congenital cytomegalovirus infection, with or without hearing loss, be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring.

The bill provides an effective date of July 1, 2024.

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, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

[35] S. 383.145(3)(e), F.S.
[36] S. 383.145(3)(l), F.S.
[37] *Supra* note 18.

The bill will negatively affect DOH due to the increase in workload for the NBHS program. DOH anticipates the need to hire one new FTE to support follow-up for the additional CCMV tests which would be necessitated by the provisions of the bill.[38] Based on a review of currently vacant positions within the Children's Medical Services Program, the department can absorb the workload within existing resources.

DOH anticipates that the Early Steps Program, the Children's Medical Services Early Intervention Program, would require increased Federal Grants trust fund authority of approximately $917,490.[39] The department has the authority to request additional federal trust fund authority up to $1,000,000 pursuant to ss. 216.181(11) and 216.212, F.S., once DOH knows how many additional children will be eligible for evaluation and monitoring.

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.[40]

D. FISCAL COMMENTS:

None.

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:

DOH has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 1, 2024, the Healthcare Regulation Subcommittee adopted an amendment to HB 499 and reported the bill favorably as a committee substitute. The amendment:

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[38] *Supra*, note 17.
[39] *Id*.
[40] Department of Health, *Agency Analysis of HB 435* (2023). On file with the Healthcare Regulation Subcommittee.

- Revised the conditions under which a newborn must be tested for CCMV; and
- Requires the receiving hospital to initiate CCMV testing for a newborn who has been transferred to another hospital for a higher level of care, unless already initiated by the birthing facility or transferring hospital.

The analysis is drafted to the bill as amended by the Healthcare Regulation Subcommittee.