HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

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

FINAL HOUSE FLOOR ACTION: 114 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 499 passed the House on March 5, 2024, as CS/SB 168.

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 in 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. Approximately 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.

The bill 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 a negative 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 was approved by the Governor on May 10, 2024, ch. 2024-164, L.O.F., and will become effective July 1, 2024.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

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.[1] 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.[2]

CMV that is present in a newborn at birth is known as congenital cytomegalovirus (CCMV). CCMV occurs when the virus is present in a pregnant woman's blood and crosses the placenta to the fetus. In severe cases, a CMV infection can cause a woman to lose her pregnancy.[3]

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.[4] Approximately 10 percent of infants with CCMV will have symptoms at birth, including:[5]

- 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).

Symptoms for CCMV are similar to those of other medical conditions, and laboratory testing within three weeks of birth is necessary to confirm CCMV. Regardless of whether symptoms are present at birth, one out of five infants with CCMV will develop long-term health problems, such as:[6]

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

Infants with CCMV may have hearing loss that is present and detectable at birth or may develop later, even in infants who passed the newborn hearing test. Approximately 15 percent of infants with CCMV will not have signs at birth, but will later develop hearing loss.[7] Hearing loss may progress from mild to

[1] Centers for Disease Control and Prevention. *About Cytomegalovirus (CMV)*. Available at https://www.cdc.gov/cmv/overview.html (last visited March 11, 2024).
[2] *Id.*
[3] Centers for Disease Control and Prevention. *Babies Born with Congenital Cytomegalovirus (CMV)*. Available at https://www.cdc.gov/cmv/congenital-infection.html (last visited March 11, 2024).
[4] Centers for Disease Control and Prevention. *CMV Fact Sheet for Healthcare Providers*. Available at https://www.cdc.gov/cmv/fact-sheets/healthcare-providers.html (last visited March 11, 2024).
[5] *Id.*
[6] *Id.*
[7] *Id.*

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.[8]

Infants with CCMV may be treated with antiviral medications which may improve hearing and developmental outcomes.[9] Infants treated with antiviral medications must be closely monitored for possible side-effects.[10]

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.[11] 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.[12]

The NSP utilizes a multilevel screening process including a prenatal risk assessment for pregnant women, and risk factor analysis and screening for postnatal women and newborns, as well as laboratory screening for select disorders in newborns.[13] 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.[14] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[15]

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.[16] 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.[17]

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.[18] 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 amount due.[19] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[20] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[21] DOH does not bill families that do not have insurance coverage.[22]

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[8] Centers for Disease Control and Prevention. *Congenital CMV and Hearing Loss*. Available at https://www.cdc.gov/cmv/hearing-loss.html, (last visited March 11, 2024).
[9] *Supra*, note 4.
[10] *Supra*, note 8
[11] S. 383.14(1), F.S.
[12] *Id*.
[13] *Id*.
[14] Florida Department of Health, *Florida Newborn Screening 2022 Guidelines*. Available at https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited March 11, 2024).
[15] 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.
[16] S. 383.14, F.S.
[17] *Id.*
[18] S. 383.145(3)(g)1., F.S.
[19] *Id.*
[20] S. 383.145(3)(g), F.S.
[21] S. 383.145(3)(h), F.S.
[22] S. 383.14, F.S.

The Florida Genetics and Newborn Screening Advisory Council advises DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[23] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots.[24] Health care providers in hospitals and birthing centers collect drops of blood from the newborn's heel on a standardized specimen collection card which is then sent to the state laboratory for testing.[25] Point-of-care testing is used at the birthing facility to screen for the conditions which cannot be screened for with blood spot testing: pulse oximetry tests for critical congenital heart defect and hearing screening to detect hearing loss.[26] Newborns who do not pass the hearing screening must be tested for CCMV.[27]

Screening results are released to the newborn's health care provider; in the event of 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.[28]

Newborn Hearing Screening and CCMV

As a component of the NSP, all newborns must be screened for hearing loss before the newborn is discharged[29] from a hospital or other state-licensed birthing facility to prevent the consequences of unidentified disorders, unless objected to by the newborn's parent or legal guardian.[30] Hearing 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.[31] A newborn's hearing is screened using automated auditory brainstem responses or evoked otoacoustic emissions screening equipment as approved by the United States Food and Drug Administration (FDA).[32] The initial hearing screening and any medically necessary follow-up reevaluations leading to a diagnosis are a covered benefit for Medicaid patients and current law requires that all private health insurance policies and health maintenance organizations (HMOs) providing comprehensive health coverage must compensate providers at the contracted rate for such services.[33]

In 2022, the Legislature passed legislation requiring that newborns who do not pass the hearing screening be further screened for CCMV. Beginning January 1, 2023, newborns who do not pass the hearing screening must be screened for CCMV with an FDA-approved, or other diagnostically equivalent, test.[34] The protocol for CCMV testing varies slightly dependent upon where the hearing screening takes place. For newborns screened in a hospital or licensed birthing facility, the CCMV test must be administered before 21 days of age or before discharge, whichever occurs earlier.[35] For

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[23] S. 383.14(5), F.S.
[24] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Health & Human Services Committee.
[25] Florida Newborn Screening Program, *What is Newborn Screening?* Available at https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited March 11, 2024). *See also,* Florida Newborn Screening, *Specimen Collection Card*, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited March 11, 2024).
[26] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Health & Human Services Committee.
[27] S. 383.145, F.S.
[28] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Health & Human Services Committee.
[29] 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. For births occurring in a non-hospital setting, 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. S. 383.145(3)(d)-(g), F.S.
[30] 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.
[31] S. 383.145(3)(f), F.S.
[32] S. 383.145(3)(i), F.S.; see also, Florida Newborn Screening Program, *2022 Congenital Cytomegalovirus Screening Guidelines* (2022). Available at https://floridanewbornscreening.com/wp-content/uploads/CMV-Screening-Guidelines-FINAL.pdf (last visited March 12, 2024).
[33] S. 383.145(3)(k), F.S.
[34] Florida Newborn Screening Program, *2022 Congenital Cytomegalovirus Screening Guidelines* (2022). Available at https://floridanewbornscreening.com/wp-content/uploads/CMV-Screening-Guidelines-FINAL.pdf (last visited March 12, 2024).
[35] S. 383.145(3)(a), F.S.

newborns who were referred to a newborn hearing screening provider for hearing screening, it is the newborn's primary care provider's responsibility to refer the infant for the administration of a CCMV test upon a failed hearing screening.[36] After 21 days of age, it is not possible to determine whether a positive CMV screening result is from congenital or acquired CMV.[37]

Blood samples, which are used for the majority of NSP testing, cannot be used to test for CCMV, necessitating a separate process for newborns who must be screened for CCMV.[38] Currently, the only FDA-approved tests to screen for CCMV require saliva or urine samples. Best practice calls for collecting both; a saliva sample is used for primary testing, and, upon a positive test result, the urine sample is used for confirmation to avoid a false-positive result.[39]

Approximately 8,500 newborns fail the newborn hearing screening and are subsequently tested for CCMV annually.[40] In 2021, of the 8,500 newborns who did not pass their hearing screenings, 300 were diagnosed with hearing loss.[41] A child diagnosed with a permanent hearing impairment must be referred by the individual who conducted the screening to the primary care physician for medical management, treatment, and follow-up services.[42] 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 Early Steps Program for further screening and services.[43]

Florida Early Steps Program

The Children's Medical Services Early Intervention Program, commonly known as Early Steps, provides early intervention services to children ages birth to 36 months with developmental delays and disabilities or who are at-risk for developmental delay based on a medical condition.[44] Early intervention services support families and caregivers to increase their child's participation in daily activities and routines. Early Steps assesses infants and toddlers in the following domains to determine eligibility: physical, cognitive, communication, social-emotional and adaptive. Each child receives an individualized family support plan that meets the child's unique needs. Families also receive support to develop the skills and confidence needed in helping their child learn and develop.[45] 15 Local Early Steps Programs are located throughout the state to provide direct services for infants, toddlers, and their families.[46]

A CCMV diagnosis is currently included on the list of at-risk conditions for Early Steps. Documentation of an at-risk condition automatically makes a child eligible for at-risk enrollment, which includes the following services: at-risk individualized family support plan support planning, service coordination, developmental surveillance, and family support. If a developmental delay is suspected, an evaluation can be completed to determine if the child's delay meets the eligibility standard for the full scope of Early Steps services. Approximately 120 infants with CCMV are referred to Early Steps annually.[47]

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[36] S. 383.145(3)(e), F.S.
[37] Florida Newborn Screening Program, *2022 Congenital Cytomegalovirus Screening Guidelines* (2022). Available at https://floridanewbornscreening.com/wp-content/uploads/CMV-Screening-Guidelines-FINAL.pdf (last visited March 12, 2024).
[38] Florida Newborn Screening Program, *2022 Congenital Cytomegalovirus Screening Guidelines* (2022). Available at https://floridanewbornscreening.com/wp-content/uploads/CMV-Screening-Guidelines-FINAL.pdf (last visited March 12, 2024).
[39] Centers for Disease Control and Prevention. Cytomegalovirus (CMV) and Congenital CMV Infection: Laboratory Testing. https://www.cdc.gov/cmv/clinical/lab-tests.html (last visited March 12, 2024). The confirmatory test is necessary because many mothers who have been infected with CMV will shed CMV in their breastmilk, even without an active infection, which can result in a false-positive CCMV result for the infant if the saliva sample is collected after breastfeeding.
[40] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Health & Human Services Committee.
[41] Department of Health, *Agency Analysis of HB 435* (2023). On file with the Health & Human Services Committee
[42] S. 383.145(3)(l), F.S.
[43] S. 383.145(3)(l), F.S.
[44] S. 391.308, F.S.; *see also*, 34 CFR 303, for the federal Individuals with Disabilities Education Act (IDEA).
[45] Department of Health, Early Steps. Available at https://www.floridahealth.gov/programs-and-services/childrens-health/early-steps/index.html (last visited March 12, 2024).
[46] Department of Health, *Agency Analysis of HB 499* (2024). On file with the Health & Human Services Committee.
[47] *Id*.

Effect of the Bill

The bill 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.

DOH estimates that an additional 31,000 infants will be referred for CCMV testing annually under the provisions of the bill.[48] Of the 31,000 additional infants who are tested for CCMV under the bill, DOH estimates that 2.1 percent, or 651 infants, will test positive for CCMV.[49]

When an infant is transferred to another facility for a higher level of care, the bill requires the receiving hospital to initiate the CCMV screening, 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 adds CCMV screening and diagnosis to the requirement in current law that hearing screening and medically necessary follow-up reevaluations leading to a diagnosis are covered benefits for Medicaid patients and for which private health insurance policies and HMOs providing comprehensive health coverage must compensate providers at the contracted rate.

The bill also requires DOH to refer children diagnosed with a CCMV infection, with or without hearing loss, to the Early Steps program.[50] Such children are eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring through Early Steps. DOH estimates that this will significantly increase the number referrals and enrollments in the Early Steps program for CCMV positive infants from approximately 120 to 771 newborns annually.[51]

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has a negative fiscal impact on DOH due to the increase in workload for the NBS 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.[52] Based on a review of currently vacant positions within the Children's Medical Services Program, the department can absorb the workload within existing resources.

[48] *Id*.
[49] *Id*.
[50] Referred to in the bill as the Children's Medical Services Early Intervention Program; *see*, s. 391.308, F.S.
[51] *Id*.
[52] *Id.*

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.[53] 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 ranges 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.[54]

D. FISCAL COMMENTS:

None.

[53] *Id*.
[54] *Id*.