

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 Committee on Health Policy

BILL: CS/SB 168

INTRODUCER: Health Policy Committee and Senator Polsky

SUBJECT: Congenital Cytomegalovirus Screenings

DATE: January 24, 2024 **REVISED:** _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------|----------------|-----------|---------------|
| 1. | Looke | Brown | HP | Fav/CS |
| 2. | | | AHS | |
| 3. | | | FP | |

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 168 amends newborn health screening requirements in s. 383.145, F.S., to require that all newborns who are born in a hospital that provides neonatal intensive care services and who are born before 35 weeks gestation, require cardiac care, or require medical or postsurgical treatment for at least three weeks, be tested for the Cytomegalovirus (CMV). Additionally, the bill requires that if the newborn is transferred to another hospital for higher level care, the receiving hospital must administer the CMV test if the test was not already performed at the transferring hospital or birth facility. The bill also requires a CMV test if the newborn will be transferred or admitted for intensive and prolonged care, regardless of whether the newborn failed his or her hearing screening.

The bill creates a new requirement that CMV screening and medically necessary follow-up reevaluations leading to diagnosis are covered benefits for Medicaid patients and that private health insurance policies and health maintenance organizations (HMO) that provide comprehensive coverage must compensate providers for the covered benefit at the contracted rate. The bill provides that a child who is diagnosed with CMV must be referred to a primary care physician and to the Children’s Medical Services (CMS) Early Intervention Program for management of his or her condition.

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

II. Present Situation:

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 already 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 (variety) of the virus. Most people with CMV infection have no symptoms and aren't aware that they have been infected.²

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 baby. This can happen when a pregnant woman is infected with CMV for the first time or is infected with CMV again during pregnancy.³

Some babies 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 baby (pregnancy loss).

Some babies with congenital CMV infection have signs at birth. These signs include:

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

Some babies with signs of congenital CMV infection at birth may have long-term health problems, such as:

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

Some babies 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 babies who passed the newborn hearing test.⁴

¹ About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cmV/overview.html> (last visited Jan. 18, 2024).

² *Id.*

³ Babies Born with Congenital Cytomegalovirus (CMV), Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cmV/congenital-infection.html>, (last visited Jan. 18, 2024).

⁴ *Id.*

CMV is the most common infectious cause of birth defects in the United States. About one out of 200 babies is born with congenital CMV. One out of five babies 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.

Babies who show signs of congenital CMV disease can be treated with medicines called antivirals. Antivirals may decrease the severity of hearing loss. Babies who get treated with antivirals should be closely monitored by their doctor because of possible side effects.⁵

Newborn and Infant Hearing Screening

Section 383.145, F.S., requires that a newborn hearing screening must be conducted on all newborns in hospitals in this state on birth admission. 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.⁶

Before a newborn is discharged from the hospital or other state-licensed birthing facility that provides maternity and newborn care services, and unless objected to by the parent or legal guardian,⁷ the newborn must be screened for the detection of hearing loss to prevent the consequences of unidentified disorders.⁸ Additionally, within 30 days of discharge from the hospital, each such facility must refer the newborn to a licensed audiologist, physician, or hospital for screening for detection of hearing loss.⁹ If the birth is a home birth, the health care provider in attendance must provide the referral to a licensed audiologist, hospital, or other newborn hearing screening provider within 30 days.¹⁰

Section 383.145, F.S., also requires that all screenings be conducted by a licensed audiologist, a licensed physician, or appropriately supervised individual who has completed documented training specifically for newborn hearing screening.¹¹ 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).¹²

If a newborn fails his or her hearing screening, the hospital or birthing facility must administer a test approved by the FDA, or other diagnostically equivalent test, to screen for CMV before the newborn becomes 21 days old or before discharge, whichever is sooner. A child who is diagnosed as having a permanent hearing impairment must be referred to the primary care

⁵ Congenital CMV and Hearing Loss, Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cmV/hearing-loss.html>, (last visited Jan. 17, 2024).

⁶ Section 383.145(3)(i), F.S.

⁷ Section 383.145(3)(c), F.S.

⁸ Section 383.145(3)(a), F.S.

⁹ Section 383.145(3)(b), F.S.

¹⁰ Section 383.145(3)(d), F.S.

¹¹ Section 383.145(3)(e), F.S.

¹² Section 383.145(3)(h), F.S.

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 serving the geographical area in which the child resides.¹³ Any person who is 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.¹⁴

Early Steps

Early Steps is Florida's early intervention system that offers services to eligible infants and toddlers, from birth to 36 months, who have or are at-risk for developmental disabilities or delays. Early intervention supports families and caregivers to increase their child's participation in daily activities and routines that are important to the family. Fifteen local Early Steps offices throughout the state receive referrals from various primary referral sources. Infants and toddlers are assessed in the following developmental domains to determine eligibility: physical, cognitive, communication, social-emotional and adaptive. Each child receives an Individualized Family Support Plan that meets his or her unique needs. Families also receive support to develop the skills and confidence needed in helping their child learn and develop.¹⁵

Medicaid and Private Health Insurance Coverage

Section 383.145(3)(k), F.S., currently requires that the initial procedure for screening the hearing of the newborn or infant and any medically necessary follow-up reevaluations leading to diagnosis are a covered benefit for Medicaid patients and that all private health insurance policies and health maintenance organizations providing comprehensive health coverage must compensate providers for the covered benefit at the contracted rate.

Mandated Health Insurance Coverages

Section 624.215, F.S., requires 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, to submit to the AHCA and the legislative committees having jurisdiction, a report that assesses the social and financial impacts of the proposed coverage. As of January 22, 2024, Senate Committee on Health Policy staff has not received this report.

Under the federal Patient Protection and Affordable Care Act (ACA), individuals and small businesses can shop for health insurance coverage on the federal marketplace. All non-

¹³ Section 383.145(3)(k), F.S.

¹⁴ Section 383.145(3)(l), F.S.

¹⁵ Early Steps, Florida Department of Health, available at <https://www.floridahealth.gov/programs-and-services/childrens-health/early-steps/index.html#:~:text=Early%20Steps%20is%20Florida's%20early,for%20developmental%20disabilities%20or%20delays> (last visited Jan. 19, 2024).

grandfathered plans¹⁶ must include minimum essential coverage (MEC),¹⁷ including an array of services that includes the 10 essential health benefits (EHBs). These 10 EHBs are further clarified or modified each year through the federal rulemaking process and are open for public comment before taking effect. The 10 general categories for the EHBs are:

- Ambulatory services (outpatient care);
- Emergency services;
- Hospitalization (inpatient care);
- Maternity and newborn care.
- Mental health and substance abuse disorder services;
- Prescription drugs.
- Rehabilitative services and rehabilitative services and devices;
- Laboratory services;
- Preventive care and chronic disease management; and
- Pediatric services, including oral and vision care.¹⁸

States are free to modify the EHBs offered in their states by adding coverage; however, because of concerns that federal funds would be used on costly mandated coverages that were not part of the required EHBs, the ACA contains a provision requiring that, starting in 2016, the states would have to pay for the cost of the coverage. As a result, the State of Florida may be required to defray the costs of any additional benefits beyond the required EHBs put in place after 2011.¹⁹

Examples of health insurance benefits mandated under Florida law include:

- Coverage for certain diagnostic and surgical procedures involving bones or joints of the jaw and facial region (s. 627.419(7), F.S.);
- Coverage for bone marrow transplants (s. 627.4236, F.S.);
- Coverage for certain cancer drugs (s. 627.4239, F.S.);
- Coverage for any service performed in an ambulatory surgical center (s. 627.6616, F.S.);
- Diabetes treatment services (s. 627.6408, F.S.);
- Osteoporosis (s. 627.6409, F.S.);
- Certain coverage for newborn children (s. 627.641, F.S.);
- Child health supervision services (s. 627.6416, F.S.);
- Certain coverages related to mastectomies (s. 627.6417, F.S.);
- Mammograms (s. 627.6418, F.S.); and
- Treatment of cleft lip and cleft palate in children (s. 627.64193, F.S.).

¹⁶ A “grandfathered health plan” are those health plans, both individual and employer plans, that maintain coverage that were in place prior to the passage of the PPACA or in which the enrollee was enrolled on March 23, 2010 while complying with the consumer protection components of the PPACA. If a group health plan enters a new policy, certificate, or contract of insurance, the group must provide the new issuer the documentation from the prior plan so it can be determined whether there has been a change sufficient to lose grandfather status. *See* 26 U.S.C. 7805 and 26 C.F.R. s. 2590.715-1251(a).

¹⁷ To meet the individual responsibility provision of the ACA statute, a benefit plan or coverage plan must be recognized as providing minimum essential coverage (MEC). Employer based coverage, Medicaid, Medicare, CHIP (i.e. Florida KidCare), and TriCare would meet this requirement.

¹⁸ 42 U.S.C. s. 18022(b)(1)(A)-(J).

¹⁹ *See* 42 U.S.C. s. 18031(d)(3)(B)(ii).

Florida's current EHB includes anti-viral medications for CMV.²⁰

III. Effect of Proposed Changes:

CS/SB 168 amends s. 383.145, F.S. to require each hospital that provides neonatal intensive care services to administer an FDA-approved test for CMV, or other diagnostically equivalent test, to each newborn admitted to the hospital as the result of a premature birth prior to 35 weeks gestation, for cardiac care, or for medical or postsurgical treatment requiring an anticipated stay of three weeks or longer. The CMV screening must be initiated prior to the newborn being 21 days of age.

The bill requires that if the newborn is transferred to another hospital for higher level care, the receiving hospital must administer the CMV test if the test was not already performed at the transferring hospital or birth facility. The bill also requires a CMV test if the newborn will be transferred or admitted for intensive and prolonged care, regardless of whether the newborn failed his or her hearing screening.

The bill amends s. 383.145(3)(k), F.S., to create a new requirement that CMV screening and medically necessary follow-up reevaluations leading to diagnosis are covered benefits for Medicaid patients and that private health insurance policies and HMOs providing comprehensive health coverage must compensate providers for the covered benefit at the contracted rate. The bill provides that a child who is diagnosed with CMV must be referred to a primary care physician and to the CMS Early Intervention Program for management of his or her condition 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.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

²⁰ *Id.*

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may have an indeterminate positive fiscal impact on the families of newborns who are diagnosed with CMV due to the required screening, are eligible for services, and are able to manage the condition prior to any permanent hearing loss occurring.

The bill may have an indeterminate negative fiscal impact on hospitals that are required to perform additional CMV tests due to the requirements in the bill.

C. Government Sector Impact:

The bill may have a negative fiscal impact on the DOH if the number of CMV screenings the DOH is required to perform under the newborn screening program increases due to the requirements in the bill and if more children are eligible to for the CMS Early Intervention Program. As of this writing, the DOH has not submitted an estimate of such fiscal impact.

The bill may have a fiscal impact on the Medicaid program. As of this writing, the Agency for Health Care Administration has not submitted an estimate of such fiscal impact.

The bill may have a negative fiscal impact on state government if the state is required to defray additional costs related to adding CMV screenings or treatments to the specified mandated insurance coverage.

VI. Technical Deficiencies:

None.

VII. Related Issues:

CS/SB 168 amends s. 383.145(3)(k), F.S., to create a new requirement that CMV screening and medically necessary follow-up reevaluations leading to diagnosis are covered benefits for Medicaid patients and that private health insurance policies and HMOs providing comprehensive health coverage must compensate providers for the covered benefit at the contracted rate, however, the bill is not specific as to what services are required to be covered under the medically necessary follow-up reevaluations. It may be advisable to clarify what services are required to be covered under the bill.

VIII. Statutes Affected:

This bill substantially amends section 383.145 of the Florida Statutes.

IX. 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 Policy on January 23, 2024.

The CS:

- Increases the gestational age, from 33 to 35 weeks, for the requirement that a hospital providing NICU services must administer a CMV test to infants born earlier than that gestational age;
- Removes the requirement to administer a CMV test to newborns who are small for their gestational age; and
- Moves the requirement to administer a CMV test when a newborn is being transferred for more intensive care from the birthing hospital to the hospital receiving the transfer.

- B. **Amendments:**

None.