

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 Appropriations

BILL: CS/SB 292

INTRODUCER: Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); and Senators Polsky and Book

SUBJECT: Newborn Screenings

DATE: February 11, 2022 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	Favorable
2.	<u>Gerbrandt</u>	<u>Money</u>	<u>AHS</u>	Recommend: Fav/CS
3.	<u>Gerbrandt</u>	<u>Sadberry</u>	<u>AP</u>	Fav/CS

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 292 amends section 383.14, Florida Statutes, to require a hospital or other state-licensed birthing facility to test newborns for congenital cytomegalovirus should the newborn fail his or her screening for hearing loss before the newborn is 21 days old or before discharge, whichever occurs earlier. For home births and births in a licensed birth center, if a newborn fails a hearing test, the bill requires that the newborn's primary healthcare provider must refer the newborn to be tested for CMV.

For home births and births in a licensed birth center the bill changes the timeframe in which a referral for appointment for a newborn hearing screen must occur to within 7 days after birth, rather than 30 days after birth.

The bill is expected to have a significant negative fiscal impact on the Department of Health. See section V of this analysis.

The bill takes effect on January 1, 2023.

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 Oct. 29, 2021).

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. 12, 2022).

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.⁵

Some babies 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.⁶

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.⁷

Florida's Newborn Screening Program

Florida's Newborn Screening Program (NBS) was established in 1965, and the processes are governed by ss. 383.14 and 383.145, F.S. The NBS currently screens for 57 conditions prior to discharge of the newborn from the hospital or other licensed birthing facility. Of the conditions screened, 55 conditions are screened through the collection of blood spots. Screening of the two remaining conditions, hearing loss and critical congenital heart defect (CCHD), are completed at the birthing facility through point of care testing.⁸

The newborn screening specimen card, which includes the drops of blood, is sent to the Department of Health's (department) Bureau of Public Health Laboratory (BPHL) in Jacksonville for analysis. On average, the BPHL in Jacksonville tests 250,000 specimens per year. When an abnormal blood screening result occurs, additional testing is required. The department's Division of Children's Medical Services NBS Follow-up Program contacts health care providers and parents to ensure confirmatory testing occurs.⁹

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

⁵ CMV Fact Sheet for Healthcare Providers, Centers for Disease Control and Prevention, available at [CMV Fact Sheet for Healthcare Providers | CDC](#), (last visited Jan. 12, 2022).

⁶ About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cmV/overview.html> (last visited Jan. 12, 2022).

⁷ Congenital CMV and Hearing Loss, Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cmV/hearing-loss.html>, (last visited Oct. 29, 2021).

⁸ Department of Health analysis of SB 292, 11/2/2021, on file with Senate Health Policy Committee staff.

⁹ *Id.*

screening performed and must be given information to assist them in having the screening performed within three months after the child's birth.¹⁰

Before a newborn is discharged from a hospital or other state-licensed birthing facility that provides maternity and newborn care services, and unless objected to by the parent or legal guardian,¹¹ the newborn must be screened for the detection of hearing loss to prevent the consequences of unidentified disorders.¹² 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.¹³ Before a newborn is discharged from a licensed birth center,¹⁴ 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.¹⁵ 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.¹⁶

The section 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.¹⁷ 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).¹⁸

A child who is diagnosed as having a permanent hearing impairment must be referred 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 serving the geographical area in which the child resides.¹⁹ 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.²⁰

¹⁰ Section 383.145(3)(i), F.S.

¹¹ Section 383.145(3)(c), F.S.

¹² Section 383.145(3)(a), F.S.

¹³ Section 383.145(3)(f), F.S.

¹⁴ Section 383.302(2), F.S., defines a "birth center" as any facility, institution, or place, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.

¹⁵ Section 383.145(3)(b), F.S.

¹⁶ Section 383.145(3)(d), F.S.

¹⁷ Section 383.145(3)(e), F.S.

¹⁸ Section 383.145(3)(h), F.S.

¹⁹ Section 383.145(3)(k), F.S.

²⁰ Section 383.145(3)(l), F.S.

III. Effect of Proposed Changes:

Cytomegalovirus

The bill amends s. 383.145, F.S., to require a hospital or other state-licensed birthing facility to administer a FDA approved test, or other diagnostically equivalent test, on a newborn to screen for congenital cytomegalovirus (CMV) 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.

For home births and births in a licensed birth center, if a newborn fails a hearing test, the bill requires that the newborn's primary healthcare provider must refer the newborn to be tested for CMV. This allows pediatricians to refer newborns for a CMV test, rather than provide the tests themselves.

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

Newborn and Infant Hearing Screening

Hospital and Licensed Birthing Center Births

Current law requires that all newborns delivered in a hospital or other state-licensed birthing facility must have a hearing screen 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.

The bill clarifies that newborns delivered in a licensed birth center must be referred to a newborn hearing screening provider before discharge.

Home Births

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 and that the referral for appointment must be made within 30 days after the birth. The bill requires that the healthcare provider in attendance must make a referral for appointment be made within 7 days after birth. In cases in which a home birth is not attended by a health care provider the bill requires that the newborns primary health care provider be responsible for coordinating a referral for a hearing test.

Under current law, parents of newborns who are not delivered in a hospital must be instructed on the importance of having a hearing screening performed within three months after birth. Persons who cannot afford the cost of a hearing test must be provided a list of newborn hearing screening providers who provide the testing for free. The bill deletes both of these provisions.

Current law defines a "licensed health care provider" as a physician licensed under chapter 458 or 459, F.S., a nurse licensed pursuant to chapter 464, F.S., or an audiologist licensed pursuant to

chapter 468, F.S., rendering services within the scope of his or her license. The bill amends this definition to include a licensed physician assistant, a midwife licensed under chapter 467, F.S., and a speech language pathologist.

The bill defines the terms audiologist, hospital, and physician for clarity in the section. The bill also makes conforming changes and deletes obsolete provisions.

The bill takes effect on January 1, 2023.

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.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/SB 292 will have a significant negative fiscal impact on the department. The department estimates a potential general revenue impact of \$440,749 (\$372,153

recurring, and \$68,596 nonrecurring), and four FTE to implement the provisions of the bill.^{21,22}

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 383.145 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Appropriations on February 9, 2022:

The committee substitute:

- Deletes a requirement in the underlying bill that each newborn be tested for congenital cytomegalovirus before becoming three weeks of age.
- Amends the definition of a licensed health care provider to include a licensed physician assistant, a midwife licensed under chapter 467, and a speech language pathologist.
- Deletes a requirement in the underlying bill that hospitals must administer a specific congenital cytomegalovirus test and instead requires a FDA approved test.
- Deletes “physician” from the list of providers that a licensed birth center must refer a newborn to for a hearing test, and that a healthcare provider in attendance of a home birth must refer a newborn to for a hearing test. For home births, this change reverts the bill language back to original statutory language.
- Requires a licensed birth center to refer a newborn for a hearing test within 7 days after discharge, rather than 30 days after discharge.
- For home births, requires that the health care provider in attendance must make a referral for appointment for a hearing screen within 7 days, instead of 30 days, after birth. In cases in which a home birth is not attended by a health care provider the bill requires that the newborns primary health care provider be responsible for coordinating a referral for a hearing test.
- Deletes a requirement from the underlying bill that primary care providers must ensure that newborns in their care whose birth was not attended to by a health care provider are screened for hearing loss within 21 days after birth.

²¹ Email from Andrew Love, Legislative Planning Director, Florida Department of Health, to Jay Howard, Senior Legislative Analyst, Florida Senate (Jan 10, 2022) (on file with the Senate Appropriations Committee on Health and Human Services).

²² Florida Department of Health, Senate Bill 292 Legislative Bill Analysis (Jan. 20, 2022) (on file with the Senate Appropriations Committee on Health and Human Services).

- Deletes a requirement from the underlying bill that primary providers must administer a FDA approved, or diagnostically equivalent, congenital cytomegalovirus test on newborns who fail their hearing screen, before the newborn is 21 days of age.
- For home births and births in a licensed birth center, if a newborn fails a hearing test, the bill requires that the newborn's primary healthcare provider must refer the newborn to be tested for CMV. This change allows pediatricians to refer newborns for a CMV test, rather than provide the tests themselves.
- Requires a hearing screening to be conducted within 21 days, instead of 30 days, if due to scheduling or temporary staffing issues a newborn cannot be screened prior to discharge from a hospital.
- Requires that the results of a newborn hearing screening and congenital cytomegalovirus and any related diagnostic testing to be reported to the department within 7 days after receipt of such results.
- Deletes a provision related to a requirement that the parents of newborns not delivered in a hospital be notified of the importance of having a hearing screening.
- Deletes a provision related to a requirement that persons who cannot afford the cost for testing be provided a list of newborn hearing screening providers who provide the testing for free.
- Changes the effective date of the bill to January 1, 2023.
- Makes conforming changes and deletes obsolete provisions.

B. Amendments:

None.