

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: SB 292

INTRODUCER: Senators Polsky and Book

SUBJECT: Newborn Screenings

DATE: February 8, 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>	Pre-meeting

I. Summary:

SB 292 amends section 383.14, Florida Statutes, to require that each newborn be tested for congenital cytomegalovirus before becoming three weeks of age. Additionally, the bill amends section 383.145, Florida Statutes, to require a hospital or other state-licensed birthing facility to administer a urine polymerase chain reaction test, or other diagnostically equivalent test, on a newborn to screen for cytomegalovirus should the newborn fail his or her screening for hearing loss. The screening for hearing loss is required under current law to be administered prior to being discharged from the hospital or birthing facility.

The bill also adds physicians to the list of facilities and practitioners to whom a parent may be referred to obtain the required newborn hearing screening after a home birth.

Given the clarity issues detailed in the “Related Issues” section of this analysis, the Department of Health has provided a range of potential fiscal impacts on the state from \$286,037 to \$19,603,864. See section V of this analysis.

The bill takes effect on July 1, 2022.

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.

¹ About Cytomegalovirus (CMV), Centers for Disease Control and Prevention, available at <https://www.cdc.gov/cmV/overview.html> (last visited Oct. 29, 2021).

A person can also be re-infected with a different strain (variety) of the virus. Most people with CMV infection have no symptoms and are not 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

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

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.*

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).

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 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 Before a newborn is discharged from a licensed birth

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.*

¹⁰ s. 383.145(3)(i), F.S.

¹¹ s. 383.145(3)(c), F.S.

¹² s. 383.145(3)(a), F.S.

center, 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.¹³ 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.¹⁴

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.¹⁵ 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.¹⁶

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.¹⁷ 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.¹⁸

III. Effect of Proposed Changes:

The bill amends s. 383.14, F.S., to require that each newborn be tested for congenital cytomegalovirus before becoming three weeks of age.

Additionally, the bill amends s. 383.145, F.S., to require a hospital or other state-licensed birthing facility to administer a urine polymerase chain reaction test, or other diagnostically equivalent test, on a newborn to screen for cytomegalovirus should the newborn fail his or her screening for hearing loss that is required under current law to be administered prior to being discharged from the hospital or birthing facility. The bill also adds physicians to the list of facilities and practitioners to whom a parent may be referred to for obtaining the required newborn hearing screening after a home birth.

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

The bill provides an effective date of July 1, 2022.

¹³ s. 383.145(3)(b), F.S.

¹⁴ s. 383.145(3)(d), F.S.

¹⁵ s. 383.145(3)(e), F.S.

¹⁶ s. 383.145(3)(h), F.S.

¹⁷ Section. 383.145(3)(k), F.S.

¹⁸ Section. 383.145(3)(l), F.S.

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:

Given the clarity issues detailed in the “Related Issues” section of this analysis, the department has provided a range of potential fiscal impacts on the state, from \$286,037 to \$19,603,864 (mix of recurring and nonrecurring). The significant range in fiscal impact is mostly due to the number of CMV tests that would need to be performed. The estimated cost for CMV testing by urine polymerase chain reaction is \$70 per test.¹⁹

The department indicates that if the bill intends that only newborns who fail their hearing screenings be tested for CMV, approximately 9,500 tests per year, and that the tests be fully conducted by the hospital or other licensed birthing facility then the department estimates a potential fiscal impact of \$372,153 recurring, and \$68,596 nonrecurring, and four FTE.²⁰

¹⁹ Department of Health analysis of SB 292, 11/2/2021, on file with Senate Health Policy Committee staff.

²⁰ 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).

If the bill intends that only newborns who fail their hearing screenings be tested for CMV, approximately 9,500 tests per year, and that the tests be conducted by the BPHL in Jacksonville, then the department estimates a potential fiscal impact of \$1,494,036 recurring and \$988,792 nonrecurring.

Finally, if the bill intends that all newborns, approximately 250,000 tests per year, be screened for CMV and those tests be conducted by the BPHL in Jacksonville, then the department estimates a potential fiscal impact of \$18,551,125 recurring, and \$1,052,739 nonrecurring.²¹

VI. Technical Deficiencies:

None.

VII. Related Issues:

This bill requires both that all newborns in the state be screened for CMV by three weeks of age (lines 23-24), and that newborns be screened for CMV if they fail the hearing screening conducted prior to discharge from the hospital or other state licensed birthing facility (lines 95-100). As such, it is unclear whether the intent of the bill is to require all newborns be screened for CMV regardless of whether they have failed the hearing screening test, or whether the bill intends that only those newborns who fail the hearing screening should be tested.

SB 292 requires on lines 95-100 that the hospital or other licensed birthing facility conduct a specified test for CMV on a newborn who has failed his or her hearing screening prior to the newborn. In general, newborn screening test specimens are collected by the hospital or other state licensed birthing facility and sent to the BPHL in Jacksonville for analysis. Given this context, it is unclear whether the bill intends for the hospital or other licensed birthing facility to fully perform the testing for CMV or whether the facility would simply collect the specimen to be tested at the BPHL in Jacksonville. It is also unclear if a CMV test is required for those children who are screened for hearing loss outside of a hospital or licensed birthing facility.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 383.14 and 383.145.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

None.

B. Amendments:

None.

²¹ Department of Health analysis of SB 292, 11/2/2021, on file with Senate Health Policy Committee staff.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
