

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 722

INTRODUCER: Health Policy Committee and Senator Garcia

SUBJECT: Newborn Health Screening

DATE: March 11, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	Fav/CS
2.			CF	
3.			JU	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 722 expands the list of health care providers who may receive the results of a newborn’s hearing or metabolic tests or screenings from the State Public Health Laboratory and revises the definition of “hearing impairment” to conform to national standards. The bill creates a new section of law directing health care practitioners who diagnose a child with hearing loss to offer the parent or guardian an opportunity to receive information about services directly from specified providers. The bill also makes two technical corrections, deleting an obsolete date and updating a cross-reference to federal law.

II. Present Situation:

Newborn Screening

Newborn screening (NBS) is a preventive public health program that provides early identification of rare genetic, metabolic, hormonal, and functional disorders among infants and follow-up care for those affected. Babies with these conditions appear healthy at birth, but can develop serious medical problems later in infancy or childhood. Without treatment, the screened-for disorders can result in significant health consequences and in some cases, death. Virtually all¹ newborns in the United States are screened and only for disorders for which there is documented benefit to the infant from early detection and for which there is a reliable screening test that is feasible in a public health setting.

¹ Florida’s newborn screening statute allows a parent to refuse the test. (s. 383.14(4), F.S.)

NBS began in the 1960s with testing for phenylketonuria (PKU). In 2002, the Maternal and Child Health Bureau of the Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services, commissioned the American College of Medical Genetics (ACMG) to develop a report outlining a process to standardize guidelines for newborn screenings. At the time, some state programs were screening for as few as five conditions and others as many as 50. The ACMG panel recommended 29 conditions as part of a core screening panel. Two additional conditions were recommended in 2010 by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).² The Secretary has adopted all 31 conditions as part of the Recommended Uniform Screening Panel (RUSP). Although states are not required to adopt the RUSP, all states currently screen for the substantial majority of the RUSP core conditions.³

Florida Newborn Screening

Florida's NBS program is administered by the Department of Health (DOH). It began in 1965 with testing for Phenylketonuria and has since expanded to cover 37 conditions, including all of the core conditions contained on the RUSP. Florida's NBS program requires that all babies born alive be tested before one week of age.⁴ Before leaving the hospital or other birthing facility, a few drops of blood are taken from the heel of the baby and the baby's ears are also tested for hearing. The hospital or birthing facility sends the blood sample to the State Public Health Laboratory (lab) in Jacksonville. The lab sends all test results back to the hospital or birthing facility, which, in turn, is required to forward them to the baby's physician.⁵ Physicians can also get results for their patients from the Florida Newborn Screening Results website. If the screening results are abnormal, the Newborn Screening Follow-up Program, which is a part of Children's Medical Services (CMS), contacts the parent and/or the physician about additional testing and continues follow-up until the disorder is either ruled out or confirmed.⁶

Current law prohibits the release of DNA testing results, whether held by a public or private entity, without the consent of the person tested, except for purposes of criminal prosecutions or paternity determinations. In addition, records held by a public entity are exempt from disclosure under Florida's public records laws. A person who commits a violation of the confidentiality requirements is guilty of a first degree misdemeanor.⁷ Notwithstanding this or any other law to the contrary, the lab may release NBS results either directly or indirectly through CMS to the

² The SACHDNC was chartered in February 2003 to advise the Secretary of the U.S. Department of Health and Human Services regarding the most appropriate application of technologies, policies, guidelines, and standards for effectively reducing morbidity and mortality in newborns and children who have or are at risk for heritable disorders. (Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, *2011 Annual Report to Congress*, available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecommendations/reports/sachdnc2011report.pdf> (last visited Feb. 17, 2014).

³ National Newborn Screening and Genetics Resource Center, *National Newborn Screening Status Report* (Jan. 1, 2013), available at <http://genes-r-us.uthscsa.edu/sites/genes-r-us/files/nbsdisorders.pdf> (last visited Feb. 18, 2014). Critical Congenital Heart Disease and Severe Combined Immunodeficiency are the two conditions that are part of the RUSP, but implemented by only a minority of states.

⁴ Section 383.14(2), F.S., Rule 64C-7.002, F.A.C.

⁵ Rule 64C-7.005, F.A.C.

⁶ Florida Department of Health, *Newborn Screening*, <http://www.floridahealth.gov/healthy-people-and-families/childrens-health/newborn-screening> (last visited Feb. 17, 2014).

⁷ Section 760.40(2), F.S.

newborn's primary care physician.⁸ Other practitioners may be involved in the care and treatment of the newborn but, because of the narrow language in the statute, cannot be granted access to the Florida Newborn Screening Results website.⁹

Newborn and Infant Hearing Screening

The Centers for Disease Control (CDC) has been tracking the number of children with hearing loss since the 1980s. The information assists in identifying risk factors for hearing loss and helps health departments, service providers, and early intervention programs to estimate case loads, plan for services, and advocate for needed resources. The CDC's Early Hearing Detection and Intervention (EHDI) program works with states to ensure that infants are screened for hearing loss no later than 1 month of age, infants who do not pass the screening for hearing loss get a full hearing evaluation no later than 3 months of age, and infants with a hearing loss receive intervention services no later than 6 months of age.¹⁰

The EHDI, in collaboration with partners that included state EHDI programs, the HRSA, and other stakeholders, has developed a survey instrument to collect standardized data from state EHDI programs about the screening, diagnostic, and intervention status of all newborns. The survey is voluntary, but serves as the primary national source of hearing screening and follow-up related data.¹¹

Currently, the EHDI survey is based on the classification system adopted by the American Speech-Language-Hearing Association (ASHA).^{12,13} The system classifies hearing loss in decibels (dB HL) as follows:¹⁴

- Normal (-10 to 14 dB HL)
- Slight (16 to 25 dB HL)
- Mild (26 to 40 dB HL)
- Moderate (41 to 55 dB HL)
- Moderately severe (56 to 70 dB HL)
- Severe (71 to 90 dB HL)
- Profound (91+ dB HL)

⁸ Section 383.14(1)(c), F.S.

⁹ Florida Department of Health, *Senate Bill 722 Legislative Bill Analysis* (Jan. 24, 2014) (on file with the Senate Health Policy Committee).

¹⁰ Centers for Disease Control, *Hearing Loss in Children*, <http://www.cdc.gov/ncbddd/hearingloss/about.html> (last visited Feb. 27, 2014).

¹¹ Email from Marcus Gaffney, MPH, Health Scientist, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (Feb. 19, 2014) (on file with the Senate Health Policy Committee).

¹² Email from Marcus Gaffney, MPH, Health Scientist, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention to Pam Tempson, Florida Department of Health (March 1, 2013) (on file with the Senate Health Policy Committee).

¹³ ASHA is the national professional, scientific, and credentialing association for more than 166,000 members and affiliates who are audiologists, speech-language pathologists, speech, language, and hearing scientists, audiology and speech-language pathology support personnel, and students. (American Speech-Language Hearing Association, *About the American Speech-Language-Hearing Association (ASHA)* <http://www.asha.org/about/> (last visited Feb. 27, 2014)).

¹⁴ American Speech-Language-Hearing Association, *Type, Degree, and Configuration of Hearing Loss* (2011), available at <http://www.asha.org/uploadedFiles/AIS-Hearing-Loss-Types-Degree-Configuration.pdf> (last visited Feb. 17, 2014).

Florida Newborn Hearing Screening

The 2000 Legislature created the Newborn and Infant Hearing Screening program with the goal of screening “all newborns for hearing impairment in order to alleviate the adverse effects of hearing loss on speech and language development, academic performance, and cognitive development.”¹⁵ The program is implemented as a component of the NBS program.

All hearing screenings must be conducted by a licensed audiologist or physician, or appropriately supervised individual who has completed training specifically for newborn screening.¹⁶ Any child who is diagnosed as having a permanent hearing impairment¹⁷ must be referred to a primary care physician for medical management, treatment, and follow up services.¹⁸

In addition and in accordance with the Individuals with Disabilities Education Act (act),¹⁹ a child up to the age of 3 years of age who is diagnosed as having a hearing impairment that requires ongoing special hearing services must be referred to the DOH Children’s Medical Services early intervention program (Early Steps). Early Steps is Florida’s program for providing services to eligible infants and toddlers with significant delays or a condition likely to result in a developmental delay. Special services provided by Early Steps include assistive technology, speech therapy, and developmental therapy. Funding for the program is a combination of federal, state (general revenue and Medicaid), and private for those children with insurance coverage.²⁰

III. Effect of Proposed Changes:

Section 1 authorizes the lab to release the results of a newborn’s hearing and metabolic tests or screenings to the newborn’s health care practitioner. “Health care practitioner,” for purposes of this provision, is defined as a physician or physician assistant, advanced registered nurse practitioner, registered nurse or licensed practical nurse, midwife, speech-language pathologist or audiologist, or dietician or nutritionist.

Section 2 changes the definition of “hearing impairment” to a loss of 16 dB HL or greater, to capture slight hearing loss, consistent with the classification system adopted by the American Speech-Language-Hearing Association. The bill deletes a reference to October 1, 2000, which was the deadline for hospitals to implement newborn hearing screening. Full implementation has occurred and the date is now obsolete. The bill updates a reference to part C of the act, which relates to Infants and Toddlers with Disabilities.

Section 3 creates a new section of law that directs health care practitioners to offer parents and legal guardians of children who are diagnosed as having a permanent hearing impairment the opportunity to receive information from providers or institutions that offer speech and language

¹⁵ Section 383.145, F.S.

¹⁶ Section 383.145(3)(e), F.S.

¹⁷ “Hearing impairment” is defined as a loss of 30dB HL or greater in the frequency region important for speech recognition and comprehension in one or both ears, approximately 500 through 4,000 hertz. (s. 383.145(2)(c), F.S.)

¹⁸ Section 383.145(3)(k), F.S.

¹⁹ The act governs how states and public agencies provide early intervention, special education, and related services to children with disabilities. Children ages birth to 2 years are covered under part C of the act, relating to Infants and Toddlers with Disabilities. The act was reauthorized in 2004. (Pub. Law No. 108-446, H.R. 1350, 108th Cong. (Dec. 3, 2004)).

²⁰ Conversation with Renee Jenkins and Pam Tempson, Florida Department of Health, (Feb. 25, 2014).

pathology services, auditory-oral education, instruction with American Sign Language, or other services as approved by rule of the Department of Health. The health care practitioner must obtain signed consent and fax the consent form to those providers and institutions that are listed with the Children's Medical Services Early Steps Program to provide services to children who are deaf or hard of hearing and that have notified the DOH of their interest in providing direct communication to families. Finally, the bill directs the DOH to post the list of providers on its website and authorizes it to adopt any necessary rules to implement and administer the section.

Section 4 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The expanded definition of "hearing impairment" may have an indeterminate fiscal impact on private insurance carriers because more children will be referred to a primary care physician for follow up services. Although it is not possible to estimate the how many children may be referred, it likely will be few since the incidence of hearing loss of any level diagnosed as a result of the screening program is small (under 300).²¹

Health care practitioners who diagnose a child as having a permanent hearing impairment will incur an indeterminate cost for the time required to transmit the contact information of parents to participating service providers.

²¹ Conversation with Lois Taylor and Pam Tempson, Florida Department of Health, (March 7, 2014).

C. Government Sector Impact:

According to the DOH²², the expanded definition will not have a fiscal impact on the state because Early Steps and Medicaid use separate criteria for determining eligibility for services. Early Steps uses a threshold of 25 dB²³ in accordance with guidelines established by the Florida Early Hearing Loss Detection Intervention Advisory Council (Council). Although the Council could change the standard, the hearing loss of a child receiving services would still need to meet the federal standard of putting the child at risk of experiencing a substantial delay if early intervention services were not provided. Medicaid uses a threshold of 40 dB.

The DOH may incur nominal costs associated with the portion of the bill related to notice to parents about services. It will be required to process requests from service providers to be on the list of those interested in providing information about services directly to families. The bill does not create an approval process, however, and only requires the DOH to confirm that the provider is on the list already maintained through the Early Steps Program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 383.14 and 383.145. The bill creates section 383.146 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 March 11, 2014:

- Creates a new section of law that directs health care practitioners to offer parents and legal guardians of children who are diagnosed as having a permanent hearing impairment the opportunity to receive information from certain service providers who are listed with the Children's Medical Services Early Steps Program to provide services to children who are deaf or hard of hearing.

²² See *supra* note 9.

²³ Florida Department of Health, Children's Medical Services, *Florida Newborn Screening Guidelines 2012*, 51, available at <http://www.floridahealth.gov/healthy-people-and-families/childrens-health/newborn-screening/documents/guidelines-final-05-24-2012small.pdf> (last visited March 7, 2014).

- Directs the DOH to post the list of providers on its website and authorizes it to adopt any necessary rules.

B. Amendments:

None.

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