Newborn screening is a preventive public health program that is provided in every state in the United States to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death. The Department of Health (DOH) is responsible for administering the statewide Newborn Screening Program, which conducts screenings for 37 disorders.

Section 383.14(1)(c), F.S., authorizes the State Public Health Laboratory to release, directly or through the Children’s Medical Services program, the results of a newborn’s hearing and metabolic tests to the newborn’s primary care physician.

The bill amends s. 383.14(1)(c), F.S., to allow the State Public Health Laboratory to release the results of a newborn’s hearing and metabolic tests or screenings to the newborn’s health care practitioner. The bill defines health care practitioner, as a physician or physician assistant, osteopathic physician or physician assistant, advanced registered nurse practitioner, registered nurse, licensed practical nurse, midwife, speech-language pathologist or audiologist, or a dietician or nutritionist.

The bill also amends s. 383.145(3)(i), F.S., and s. 383.145(3)(k), F.S., to delete obsolete language.

Finally, the bill creates a new section of law to require an audiologist, upon diagnosing an infant or toddler with a permanent hearing impairment, to offer the parent or guardian an opportunity to receive information about services directly from qualified Early Steps providers who offer early intervention services and specialize in serving children with hearing loss.

The bill does not appear to have a fiscal impact.

The bill provides an effective date of July 1, 2014.
FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Newborn Screening

Newborn screening is a preventive public health program that is provided in every state in the United States. The intent of the Florida Newborn Screening Program (NSP) is to screen all newborns for hearing impairment to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent development and physical damage or death. The Department of Health (DOH) is responsible for administering the NSP, which currently screens for 37 disorders.¹

The NSP is a comprehensive system involving coordination among several entities, including the Bureau of Laboratories Newborn Screening Laboratory in Jacksonville, Children’s Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, and referral centers throughout the state. In addition, the Genetics and Newborn Screening Advisory Council serves as an advisory body to DOH.²

Newborn screening usually takes place before a newborn leaves the hospital. Most tests use a few drops of blood from pricking the baby’s heel. The blood specimen is placed on a special filter paper and, in Florida, the specimen card is sent to the DOH Newborn Screening Laboratory in Jacksonville for testing. The laboratory receives about 250,000 specimens annually from babies born in Florida. The majority of the test results are reported within 24-48 hours. The CMS program, within DOH, provides follow-up services for all abnormal screening results.

Newborn Hearing Screening

Newborn hearing screening has been required in Florida since October, 2000.³ Newborn hearing screening services are provided to identify newborns at risk of hearing impairment and to ensure that follow-up audiometric screening, diagnosis, and referral to intervention is provided.⁴

Hospitals and other state-licensed birthing facilities that provide maternity and newborn care services are required to screen all newborns for hearing loss, prior to discharge. However, a parent or legal guardian may sign a waiver to refuse the hearing screening, and a copy of the waiver must be filed in the newborn’s medical record.⁵ If screening is not completed before discharge due to scheduling or temporary staffing limitations, or if the newborn fails the screening, the hospital must refer the newborn for screening, which must be conducted within 30 days of discharge.

Any child who is diagnosed as having a hearing impairment must be referred to their primary care physician for medical management, treatment, and follow-up services. Further, 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 CMS Early Intervention Program (Early Steps). Early Steps is Florida’s early intervention system that offers services to eligible infants and toddlers with significant delays or a condition likely to result in a developmental delay. Early intervention is provided to support families and caregivers in developing the competence and confidence to help their child learn and

¹ House Bill 591, Department of Health, Legislative Bill Analysis, January 14, 2014 (on file with Health Quality Subcommittee).
² Section 383.14(5), F.S.
³ Chapter 2000-177, L.O.F., CS/HB 399.
⁴ Sections 391.301-304, F.S., s. 383.14, F.S., and s. 383.145, F.S.
⁵ Section 383.145(3), F.S.
A diagnosis must provide evidence of a hearing loss of 25 dB or greater to be eligible for services provided by the Early Steps Program.¹

Florida law defines a hearing impairment as a hearing loss of 30 dB HL or greater.²

Pursuant to s. 383.14(1)(c), F.S., and notwithstanding any other law to the contrary, the State Public Health Laboratory may release, directly or through the CMS Program, the results of a newborn’s hearing and metabolic tests or screening to the newborn’s primary care physician.

Effect of Proposed Changes

The bill amends s. 383.14(1)(c), F.S., to allow the State Public Health Laboratory to release the results of a newborn’s hearing and metabolic tests or screenings to the newborn’s health care practitioner, not just the newborn’s physician. For purposes of this section, the bill defines “health care practitioner”, as a physician or physician assistant, osteopathic physician or physician assistant, advanced registered nurse practitioner, registered nurse, licensed practical nurse, midwife, speech-language pathologist or audiologist, or a dietician or nutritionist.

The bill amends s. 383.145(3)(i), F.S., and s. 383.145(3)(k), F.S., to delete obsolete and out of date language.

Finally, the bill creates a new section of law to require an audiologist, upon diagnosing an infant or toddler with a permanent hearing impairment, to offer the parent or legal guardian of the child an opportunity to receive information about services directly from qualified Early Steps providers who offer early intervention services and specialize in serving children with hearing loss. If the parent or legal guardian wishes to receive direct correspondence from the providers they must provide their contact information and authorize the release of the contact information by signing a consent form.

The bill requires DOH to post on its website, a list of qualified Early Steps providers of early intervention services who specialize in serving children with hearing loss and who have notified DOH of their interest to provide direct communication to families who wish to receive information about the services they provide.

Further, the bill requires the audiologist, or the audiologist’s designee, to send the consent form by secure transmission to the providers listed on the DOH website.

B. SECTION DIRECTORY:

Section 1: Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.

Section 2: Amends s. 383.145, F.S., relating to newborn and infant hearing screening.

Section 3: Creates s. 383.146, F.S., relating to infants and toddlers who are deaf or hard of hearing; and notice of service providers.

Section 4: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:
   None.

2. Expenditures:


² Section 383.14(1)(c), F.S.
B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
   None.

2. Expenditures:
   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
   None.

D. FISCAL COMMENTS:
   None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:
   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:
   None.

B. RULE-MAKING AUTHORITY:
   No additional rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:
   None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 20, 2014, the Health and Human Services Committee adopted two amendments to HB 591 and reported the bill favorably as a committee substitute. The amendment made the following changes to the bill:

- Creates a new section of law to require audiologists to offer parents and legal guardians of children who are diagnosed with a permanent hearing impairment the opportunity to receive information from qualified Early Steps providers who offer early intervention services and specialize in serving children with hearing loss.
- Requires a parent or legal guardian to sign a consent form authorizing release of their contact information, if they wish to receive the information.
- Requires DOH to post a list of the qualified providers on its website.
- Requires audiologists to send the consent form by secure transmission to the providers listed on the DOH website.

This analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.