

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 Health Regulation Committee

BILL: SB 1826

INTRODUCER: Senator Gardiner

SUBJECT: Developmental Disabilities

DATE: January 27, 2012

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	Pre-meeting
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

This bill requires a healthcare provider who diagnoses a medical condition in a fetus based on a screening test to provide the pregnant mother with current information about the conditions that were tested for, the accuracy of such tests, and resources for support services for the diagnosed disorder. The bill also creates a prenatal advisory council within the Department of Health (the department) to establish a clearinghouse of information relating to support services for pregnant mothers of fetuses with prenatally-diagnosed conditions. The Office of Vital Statistics is required to refer women at risk for preterm birth or other high-risk conditions to appropriate health, education, social services, and other support services in accordance with s. 383.141, F.S.

The bill also amends provisions concerning the John M. McKay Scholarship Program to widen eligibility criteria and increase awareness of the program among military personnel. Regional autism centers must provide information on local resources for children who have all types of developmental disabilities and support state agencies in the development of training for early child care providers and educators with respect to all developmental disabilities.

This bill creates s. 383.141, Florida Statutes, and amends ss. 383.14, 1002.39, and 1004.55, Florida Statutes.

II. Present Situation:

Prenatal Screening in Medicine¹

Prenatal testing is divided into two types, screening tests and diagnostic tests. Screening tests are safe, minimally-invasive studies performed in large, low-risk populations to detect conditions in which timely intervention can alter outcomes. Screening tests frequently produce false-positive results, so any positive finding must be confirmed with a diagnostic test.

Prenatal screening uses a combination of maternal blood tests and ultrasound to evaluate a fetus for various conditions. Diseases which may be detected on prenatal screening include Down syndrome (trisomy 21) and other trisomies; neural tube defects such as spina bifida; abdominal wall defects; kidney, skin, heart, lung, or limb malformations; ovarian tumors; abnormalities in the mother's uterus or placenta; and Tay-Sachs disease.

Diagnostic tests are more accurate, invasive, and prone to complications than screening tests. They are administered to women who have received a positive screening test result or who have risk factors or a family history for certain diseases. Such tests may involve analyzing amniotic fluid or drawing fetal blood. Diagnoses which may be made by such testing include Tay-Sachs disease, sickle-cell anemia, hemophilia, muscular dystrophy, cystic fibrosis, fetal hemolysis, Prader-Willi syndrome, thalassemia, and phenylketonuria (PKU).

More than 800 prenatal tests are available evaluate a wide range of diseases. Genetic counseling is an essential part of the testing process to keep families informed about the diagnosis, severity, and prognosis of any discovered disorder as well as available options for treatment.

Prenatal Screening in Statute

The Florida Healthy Start Program² provides for universal risk screening of all Florida's pregnant women and newborn infants to identify those at risk of poor birth, health, and developmental outcomes. Healthy Start also includes targeted support services to address identified risks, including information and referral, comprehensive assessment of service needs in light of family and community resources, ongoing care coordination and support to assure access to needed services, psychosocial, nutritional, and smoking cessation counseling, and childbirth, breastfeeding, and parenting support and education.³

Healthy Start prenatal screening focuses on improving mothers' medical or socioeconomic risk factors to create a healthier pregnancy. Factors considered in pregnant women include level of education, presence of other special needs children, marital status, mental health screening, financial hardship, drug and tobacco use, feelings about the pregnancy, and any medical problems. Healthy Start does not place any emphasis on support for those babies who have been

¹ Medscape Reference, *Prenatal Diagnosis and Fetal Therapy*, available at: <http://emedicine.medscape.com/article/936318-overview#aw2aab6b3> (last visited on January 27, 2012).

² Provisions for this program are located in s. 383.14, F.S., and related rules.

³ Department of Health, *Florida's Healthy Start*, available at: <http://www.doh.state.fl.us/Family/mch/hs/hs.html> (last visited on January 27, 2012).

given a medical diagnosis via medical prenatal screening or genetic testing.⁴ Physicians are required to administer such screening on the patient's initial pregnancy visit and report the results to the Office of Vital Statistics for further care coordination.⁵

Department screening for medical diseases occurs after the birth of the child. Specific diseases which are screened for and procedures for reporting are specified in rule. Newborns who receive a positive result on any of the disease screens are referred to appropriate healthcare professionals and support and counseling services.⁶

The department is also required to educate the public about the prevention and management of metabolic, hereditary, and congenital disorders associated with environmental risk factors; and promote the availability of genetic studies and counseling in order that the parents, siblings, and affected newborns may benefit from available knowledge of the condition.⁷ Healthy Start provides information and support concerning environmental risk factors during pregnancy, and Children's Medical Services coordinates counseling for any disorders identified during post-natal screening, but currently no programs focus on prenatally-diagnosed medical conditions.⁸

Informed Consent

Before performing any medical testing or treatments, a patient must give voluntary, informed consent to the practitioner performing the procedure. The nature of the procedure, risks, benefits, potential results, and other available options must be explained to the patient in terms that he or she can understand. The patient must also be deemed mentally competent, meaning that he or she can understand the options and their implications and be able to make his or her own decisions. If a patient is not deemed mentally competent, the person appointed to make decisions for the patient must give informed consent.

Consent is often implied for routine tests such as blood draws or X-rays but must always be explicitly given for more invasive procedures such as surgery.^{9,10}

Genetics and Newborn Screening Advisory Council

The Genetics and Newborn Screening Advisory Council (the council) was created within the department in 1980¹¹ to recommend the conditions that should be tested through newborn screening or genetic testing, the appropriate modalities to use, and how to make current testing services more coordinated and efficient. The council consists of:

- Two consumer members;
- Three pediatricians, including at least one pediatric hematologist;

⁴ Department of Health, Healthy Start Program, *Prenatal Risk Screening Form*, available at: http://www.doh.state.fl.us/Family/mch/hs/english_prenatal_screen.pdf (last visited on January 27, 2012).

⁵ Section 383.14(1)(a), F.S.

⁶ Rule 64C-7, F.A.C.

⁷ Section 383.14(3)(c) and (f), F.S.

⁸ Telephone conversations with Healthy Start, Children's Medical Services, and department legislative staff.

⁹ EMedicine Health, *Informed Consent*, available at: http://www.emedicinehealth.com/informed_consent/article_em.htm (last visited on January 27, 2012).

¹⁰ Standards of practice for informed consent are also found in Rule 64B8-9.007, F.A.C.

¹¹ Phone conversation with Florida Newborn Screening Program staff.

- One representative from each of the four medical schools in the state;
- The State Surgeon General or his or her designee;
- One representative from Children’s Medical Services;
- One representative from the Florida Hospital Association;
- One individual with experience in newborn screening programs;
- One individual representing audiologists; and
- One representative from the Agency for Persons with Disabilities.

Ad hoc or temporary technical advisory groups may be formed to assist the council with specific topics. Council members serve without pay but may be reimbursed for travel expenses.¹²

Statutory Creation of Advisory Bodies, Commissions, or Boards

The statutory creation of any collegial body to serve as an adjunct to an executive agency is subject to certain provisions in s. 20.052, F.S. Such a body may only be created when it is found to be necessary and beneficial to the furtherance of a public purpose, and it must be terminated by the Legislature when it no longer fulfills such a purpose. The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of any collegial or advisory bodies.

A committee or task force is defined in statute to mean “an advisory body created without specific statutory enactment for a time not to exceed 1 year or created by specific statutory enactment for a time not to exceed 3 years and appointed to study a problem and recommend a solution or policy alternative with respect to that problem. Its existence terminates upon the completion of its assignment.”¹³

Private citizen members of any advisory body (with exceptions for members of commissions or boards of trustees) may only be appointed by the Governor, the head of the executive agency to which the advisory body is adjunct, the executive director of the agency, or a Cabinet officer. Private citizen members of a commission or a board of trustees may only be appointed by the Governor, must be confirmed by the Senate, and are subject to the dual-office-holding prohibition of s. 5(a), Art. II of the State Constitution.

Members of agency advisory bodies serve for 4-year staggered terms and are ineligible for any compensation other than travel expenses, unless expressly provided otherwise in the State Constitution. Unless an exemption is specified by law, all meetings are public, and records of minutes and votes must be maintained.¹⁴

John M. McKay Scholarship for Students with Disabilities Program

The John M. McKay Scholarship for Students with Disabilities Program is established to provide the option to attend a public school other than the one to which assigned or to provide a

¹² Section 383.14(5)

¹³ Section 20.03(8), F.S.

¹⁴ Section 20.052, F.S.

scholarship to a private school of choice for certain students with disabilities.¹⁵ To receive such a scholarship for enrollment in a private school, a student must have been accepted to a school which is eligible to participate in the program and have:

- Received specialized instructional services as part of a public pre-kindergarten program during the previous school year and has a current individual educational plan developed by the local school board fulfilling certain criteria;
- Attended a Florida public school or the Florida School for the Deaf and Blind during the previous school year; or
- Was enrolled in a public school during any of the 5 years prior to the 2010-2011 fiscal year, has a current individual educational plan developed by the local school board fulfilling certain criteria, and receives a first-time John M. McKay scholarship for the 2011-2012 school year.

A dependent child of a member of the military who transfers to a school in this state from another jurisdiction due to a parent's permanent change of station orders is exempt from these requirements.¹⁶

The scholarship will remain in force until the student returns to a public school, graduates from high school, or reaches the age of 22, whichever comes first. If a student enters a Department of Juvenile Justice detention center for more than 21 days, this is considered as a return to public school.¹⁷

Regional Autism Centers

Seven regional autism centers exist in Florida to provide nonresidential resource and training services to people with autism, pervasive developmental disorders not otherwise specified, autistic-like disabilities, dual sensory impairments (both permanent visual and hearing impairments¹⁸), or who have a sensory impairment with other handicapping conditions. The centers are located in Tallahassee, Gainesville, Jacksonville, Tampa, Miami, Orlando, and Boca Raton and operate independently of one another to coordinate services for residents in their regions. Centers coordinate services within and between state and local agencies and school districts but may not duplicate services provided by those agencies or school districts.

Each center provides:

- Staff with expertise in autism, autistic-like behaviors, and sensory impairments;
- Individual and direct family assistance in the home, community, and school;
- Technical assistance and consultation services for a client of the center, the client's family, and the school district;
- Professional training programs for personnel who work with the populations served by the centers;

¹⁵ Students with disabilities eligible for this scholarship include K-12 students with documented intellectual disabilities, speech or language impairments, visual or hearing impairments, orthopedic impairments, other health impairments, emotional or behavioral disabilities, learning disabilities, traumatic brain injuries, developmental delay, or autism spectrum disorders. See s. 1002.39, F.S.

¹⁶ Section 1002.39(1) and (2), F.S.

¹⁷ Section 1002.39(4), F.S.

¹⁸ Section 427.703(4), F.S.

- Public education programs to increase awareness of the public about autism, autistic-related disabilities of communication and behavior, dual sensory impairments, and sensory impairments with other handicapping conditions;
- Coordination and dissemination of information regarding available resources for children with the developmental disabilities served by regional autism centers;
- Support to state agencies in the development of training for early child care providers and educators with respect to the developmental disabilities served by regional autism centers.¹⁹

III. Effect of Proposed Changes:

Section 1 creates s. 383.141, F.S. This section provides legislative intent that pregnant women who choose to undergo prenatal screening should have access to timely and informative counseling about the conditions being tested for, the accuracy of such tests, and resources for obtaining support services for such conditions. Definitions for various terms are provided.

The bill requires a healthcare provider who diagnoses a medical condition in a fetus based on a prenatal test to provide the pregnant mother with current information about the conditions that were tested for, the accuracy of such tests, and resources for support services for the diagnosed disorder. Such services include information hotlines specific to Down syndrome or other prenatally-diagnosed conditions, support groups for parents and families, information clearinghouses, and developmental evaluation and intervention services under s. 391.303, F.S.

The bill also creates a prenatal advisory council within the department to establish a clearinghouse of information relating to support services for pregnant mothers of fetuses with prenatally-diagnosed conditions. The council will consist nine members who are health care providers or caregivers who perform health care services for persons who have developmental disabilities, including Down syndrome and autism. Three members each are appointed by the Governor, the President of the Senate, and the Speaker of the House of Representatives. The council will meet quarterly and will serve without compensation, although reimbursement for travel expenses is permitted. The department will provide administrative support to the council.

Section 2 amends s. 383.14, F.S., to require that the Office of Vital Statistics refer women at risk for preterm birth or other high-risk conditions to appropriate health, education, social services, and other support services in accordance with s. 383.141, F.S., created in this bill.

Section 3 amends s. 1002.39, F.S., concerning the John M. McKay Scholarship Program. Students who were enrolled in public school during any of the 5 years prior to the 2010-2011 fiscal year, have current individualized educational plans developed by the district school board following certain conditions, and receive a John M. McKay scholarship for the 2011-2012 school year—regardless of whether it was a first-time scholarship—will be able to enroll in an eligible private school. Dependent children of military personnel who transfer to a school in Florida from another jurisdiction pursuant to a parent's permanent change of station orders must be provided information on the John M. McKay Scholarship Program by the school.

¹⁹ Section 1004.55, F.S.

Section 4 amends s. 1004.55, F.S., to require regional autism centers to provide information on local resources for children who have all types of developmental disabilities, not simply those described in subsection (1) of this section. Section 1004.55, F.S., pertains to services for persons of all ages and of all levels of intellectual functioning who have autism, pervasive developmental disorders that are not otherwise specified, autistic-like disabilities, dual sensory impairments, or sensory impairments with other handicapping conditions. Regional autism centers must also support state agencies in the development of training for early child care providers and educators with respect to all developmental disabilities.

Section 5 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Pregnant mothers of children prenatally-diagnosed with medical conditions will be better informed about the nature of the disease, treatment options, and support services. Additional children may qualify for the John M. McKay Scholarship Program, and military personnel who were reassigned to Florida will have greater awareness of the program. Families of children with all types of developmental disabilities will receive better support from regional autism centers.

C. Government Sector Impact:

Additional children may apply for the John M. McKay Scholarship Program due to increased eligibility criteria and increased awareness. Workload and costs for the department will increase related to administrative support of the prenatal advocacy council. Regional autism centers will experience an increase in workload and a negative

fiscal impact related to compiling resources and creating educational programs related to additional types of developmental disabilities.

VI. Technical Deficiencies:

The term “prenatally diagnosed condition” is broader than testing for developmental disabilities, which appears to be the focus of this bill. Other provisions in the bill could be amended for consistency.

VII. Related Issues:

Section 1004.55(1), F.S., states that regional autism centers may coordinate services within and between state and local agencies and school districts but may not duplicate services provided by those agencies or districts. The bill’s expansion of the types of developmental disabilities for which regional autism centers must provide support could go against this provision.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

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

None.

B. Amendments:

None.