

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government/Ensure Lower Taxes—The bill creates the licensure and regulation of genetic counselors in Florida.

B. EFFECT OF PROPOSED CHANGES:

Legislative History

Legislation requiring the licensure of genetic counselors in Florida was filed in 2002, 2003 and 2004. In 2003, Senate Bill 2222 was unanimously passed by the Health, Aging and Long-Term Care and Governmental Oversight and Productivity committees. Its companion, House Bill 1351, was not considered in the House. In 2004, House Bill 479 and Senate Bill 506 passed successfully through both houses, but the legislation was vetoed by Governor Bush on June 24, 2004. According to proponents of the legislation, licensing is being actively pursued in at least 14 other states, and legislation requiring licensing of genetic counselors has been adopted in California and Utah.

Genetic Counseling

According to information provided by the Florida Genetic Counselor's Network, the concept of genetic abnormalities can be frightening and confusing to patients and parents. Genetic counselors offer supportive care to patients with potential or actual genetic diseases. They work closely with obstetricians and other health care practitioners who provide maternal and family medicine. Genetic counseling helps individuals and families translate scientific knowledge into practical information. A genetic counselor is trained to help translate the information clearly, and to be an emotional resource to help affected individuals deal with situations they face.

When a birth defect is diagnosed, for example, genetic counselors provide emotional support and understanding during what can be a very difficult time. When provided with accurate and understandable information, parents are better able to make decisions about the pregnancy, care of the child, whether to have more children, or the ability of the family to cope with ongoing problems. The counselor can refer parents to other specialists and support groups in the community that deal with specific genetic conditions.

Current Challenges to Appropriate Genetic Counseling

Information provided by the Florida Genetic Counselor's Network (Florida Network) in the Sunrise Review questionnaire prepared to support licensure, indicated that as of Fall 2003, more than 1,000 genetic tests are now clinically available (Wall Street Journal, December 2003). Potential consumers of such technologies (patients and health care providers) must rely on their health care providers to explain, administer and interpret their results.

According to the Florida Network, patients who have received genetic counseling from untrained providers or who have not had access to such counseling have been harmed. The Network cites the example of patients terminating pregnancies after health care providers misinterpreted Cystic Fibrosis DNA test results, when a potentially benign polymorphism in the CFTR (Cystic Fibrosis Conductance Transmembrane Regulator) gene (the 5 T polymorphism) was interpreted as a true mutation.

The Florida Network has provided information that approximately 20,000 Floridians seek face-to-face services from the occupation each year. Although the bill specifically does not require health insurance payment, the Network argues that since state licensing will facilitate the development of reimbursement

schedules from health insurers, the proposed regulation will greatly increase the number of people with access to services from genetic counselors. According to Genetic Counselors, public access to genetic counseling services is currently restricted by the unwillingness of insurers to provide reimbursement for an unregulated profession.

Genetic Counselors in Florida

The National Society of Genetic Counseling indicates that there are approximately 50 to 60 genetic counselors in Florida and estimate that approximately 37 of that number are nationally certified. The national society indicates that the average annual salary of genetic counselors ranges from \$35,000 to \$60,000.

According to the Florida Network, patients in Florida presently pay from \$86 to \$350 per episode, depending on the length of the encounter. Based on a survey of genetic counselors in the state, the Network estimates that Master's level genetic counselors, specifically trained to provide this service, typically bill between 50 percent and 70 percent of the physician cost.

National Certification

Genetic counselors currently achieve "Board Certification" by completing an accredited training program; completing and documenting a minimum of 50 supervised clinical cases in a variety of genetic counseling clinic settings; and passing national certification exams in general genetics and genetic counseling.

National certification has been available for genetic counselors since 1993. The American Board of Genetic Counseling (ABGC) prepares and administers examinations to certify individuals who provide services in the medical genetics specialty of genetic counseling and accredits training programs in the field of genetic counseling.

Providers of genetic counseling include individuals who have followed a specific educational curriculum and who are certified genetic counselors, and doctors or nurses with special training in the subject.

Genetic counselor training programs grant a Master of Science or doctoral degree. There are 30 accredited genetic counseling training programs (twenty-two fully accredited programs, five new programs, and three programs having interim accreditation) in the United States and Canada. New programs must apply for full accreditation within one to five years after the first class of graduates. At least ten other states are pursuing state genetic counseling regulation. Two states, California and Utah, recently passed legislation regulating the practice of genetic counseling.

Statutory Sunrise Review Criteria for Consideration of Licensure

The Sunrise Act, codified in section 11.62, Florida Statute, requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The act requires that all legislation proposing regulation of a previously unregulated profession or occupation be reviewed by the Legislature based on a showing of the following:

- (1) That substantial risk of harm to the public is a risk of no regulation which is recognizable and not remote.
- (2) That the skills the profession requires are specialized and readily measurable.
- (3) That job creation or job retention will not be unreasonably affected.
- (4) That other forms of regulation do not or cannot adequately protect the public.
- (5) That the overall cost-effectiveness and economic impact of the proposed regulation is favorable.

The act requires proponents of regulation of a previously unregulated profession to provide the agency and legislative committees with information concerning the effect of proposed legislation. A Sunrise questionnaire that provides this information in support of licensure was completed by proponents in December 2004.

Current Regulatory Framework for Health Professions

Chapter 456, Florida Statutes, provides the general regulatory provisions for health care professions within the Division of Medical Quality Assurance of the Department of Health. The Division of Medical Quality Assurance regulates 37 professions and 6 facilities, and works with 22 boards and 6 councils. According to the division, this represents 91 different licensure categories and more than 750,000 licensed health care practitioners. Each profession, except those regulated directly by the department, is represented by a board or council comprising individuals licensed in that profession, as well as consumer members. The division provides administrative support to the boards as they review cases related to health care practitioner licensure and disciplinary actions. The division also helps conduct board meetings—345 per year on average.

Practitioner enforcement activities of the division include a consumer complaint call center, investigation and legal services. The program investigates complaints and assesses probable cause for each case. Cases are then presented to licensing boards and councils for final action. If a board finds that an allegation is justified, it may take disciplinary action. If a practitioner contests a finding of probable cause, the case is heard by an administrative law judge. Disciplinary measures can range from a reprimand and fine to suspension or revocation of the practitioner's license.

House Bill 1033 creates part XV, chapter 468, Florida Statutes, the "Genetic Counseling Practice Act," providing for the regulation of genetic counselors within the Department of Health by a five-member board. Legislative intent is provided that genetic counselors who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in Florida. The legislative intent section specifies that the act may not be construed to require payment from insurers for genetic counseling services.

Scope of Practice

The bill defines the practice of genetic counseling as the communication process that deals with human problems associated with a genetic disorder in a family, including services to help an individual or family:

- Comprehend the medical facts in the diagnosis, cause, and available management of a disorder.
- Appreciate the way heredity contributes to the disorder and its risk of occurrence in relatives.
- Understand the alternatives for dealing with the risk of occurrence.
- Choose the appropriate course of action.
- Make the best possible psychosocial adjustment to the disorder in an affected family member or to the risk of occurrence of the disorder.

The bill provides that a person may not practice genetic counseling or hold himself or herself out as a genetic counselor in Florida unless he or she is licensed under this act.

Exemptions

The bill allows other regulated groups such as nurses, physicians, social workers and physician assistants to continue to provide services under their scope of practice as it relates to their specialized training. Exemptions to licensure requirements are provided to public health or military officers acting within the scope of their responsibilities, and to licensed health care practitioners defined in section 456.001, Florida Statutes, who may perform genetic counseling that is consistent with their scope of practice.

The Board of Genetic Counselors

The bill creates a Board of Genetic Counselors within the Department of Health of five members appointed by the Governor and confirmed by the Senate. Three of the members must be licensed genetic counselors who are Florida residents, and the remaining two members must be consumers. The board may adopt rules to implement its duties, including rules relating to standards of practice for genetic counselors.

Licensure Requirements

To become licensed to practice genetic counseling in Florida, the bill requires that an applicant must:

- Be of good moral character.
- Complete a master's degree from a genetic counseling training program accredited by the American Board of Genetic Counseling, or a doctoral degree from a medical genetics training program accredited by the American Board of Medical Genetics.
- Pass the examination for certification as a genetic counselor by the American Board of Genetic Counseling or the American Board of Medical Genetics or as a medical or clinical geneticist by the American Board of Medical Genetics.

The bill authorizes the Department of Health to issue a temporary license to an applicant who meets all the licensure requirements except the examination requirement and is eligible to sit for the next available exam. The board must establish a procedure for approving continuing education courses and providers and may set a fee for continuing education courses and provider approval.

Fees

The bill authorizes the board to establish the following fees:

- Application—no greater than \$100.
- Initial licensure and biennial renewal—no greater than \$600.
- Inactive, delinquent, reactivation or voluntary inactive fees—no greater than \$100 each.

Sanctions

The bill creates criminal offenses for making false or fraudulent statements presented to the board; practicing genetic counseling without a license; and using the title genetic counselor unless licensed or exempt from the licensing requirements. A person who violates the prohibitions created in the bill is guilty of a second degree misdemeanor punishable by jail time of up to 60 days and the imposition of a fine of up to \$500.

The bill provides an effective date of October 1, 2005.

C. SECTION DIRECTORY:

Section 1. Creates ss. 468.901–468.913, F.S., known as the “Genetic Counseling Practice Act,” establishing the regulation of genetic counselors.

Section 2. Amends s. 20.43(3)(g), F.S., adding the Board of Genetic Counselors under the Division of Medical Quality Assurance in the Department of Health.

Section 3. Amends s. 456.001, F.S., redefining the term “health care practitioner” to include genetic counselors licensed under part XV of chapter 468, F.S.

Section 4. Provides an effective date of October 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:	FY 2005-06	FY 2006-07
Application fee (40 @ \$100)	\$4,000	
Application fee (5 @ \$100)		\$500
Licensure fee (40 @ \$600)	\$24,000	
Licensure fee (5 @ \$600)		<u>\$3,000</u>
Medical Quality Assurance Trust Fund	<u>\$28,000</u>	<u>\$3,500</u>

2. Expenditures:	FY 2005-06	FY 2006-07
Board of Genetic Counselors	\$9,000	\$2,250
Allocated expenditures	<u>\$25,000</u>	<u>\$25,000</u>
Medical Quality Assurance Trust Fund	\$34,000	\$27,250
 Surplus/(Deficit)	 (\$6,000)	 (\$24,750)

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to the department, persons seeking to practice genetic counseling in Florida will incur the expenses to meet the licensure requirements established in the bill.

D. FISCAL COMMENTS:

The Board of Genetic Counselors is authorized by the bill to establish the following fees for the regulation of genetic counseling: application, no greater than \$100; initial licensure, no greater than \$600; biennial renewal, no greater than \$600; and inactive, delinquent, reactivation, or voluntary inactive licensure status, all of which may be no greater than \$100. The department assumes that 40 genetic counselors will apply for Florida certification during Fiscal Year 2005-2006 and assumes that only five applicants will apply during Fiscal Year 2006-2007

According to the Department of Health, there will be four meetings in which five board members would be entitled to \$50 compensation and an average reimbursement of \$400 travel, per diem, and hotel expenses. During fiscal year 2006-2007, the department estimates that the board will hold at least one meeting. In addition to these direct costs for the board, there will be "allocated expenditures" recognized by s. 456.025(8), F.S., as expenditures which cannot be directly charged to a profession. The department estimates there will be an additional \$25,000 annually of "allocated expenditures" needed to cover other regulatory services provided by the department for regulation of genetic counseling. These allocated expenditures are "direct services" provided by other Medical Quality Assurance (MQA) licensure functions, including handling of applications, establishing the practitioner database, costs of investigations, prosecutions and administrative hearings, the impaired practitioner program, and so on. Each quarter, the department collects statistics from a variety of sources to fairly and appropriately allocate expenditures.

The department reports that expenditures for the two year-projected period would total \$61,250, and the revenues would total \$31,500. The department also reports with certainty that the board would operate at a deficit posture because of the small number of persons seeking licensure and fee cap. Section 456.025(3), F.S., requires that each licensed health profession shall ensure that license fees are adequate to cover all anticipated costs of licensure and maintain a reasonable cash balance.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Board of Genetic Counseling with rulemaking authority to implement the provisions of the bill. The department will have rulemaking authority under current section 456.004, Florida Statutes

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES