

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 479 Genetic Counselors
SPONSOR(S): Cusack
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/CS/SB 506 (s)

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|--------------------------------|----------|----------|----------------|
| 1) Health Standards (Sub) | 8 Y, 0 N | Mitchell | Collins |
| 2) Health Care | | | |
| 3) Finance & Tax | | | |
| 4) Health Appropriations (Sub) | | | |
| 5) Appropriations | | | |

SUMMARY ANALYSIS

HB 479 provides for licensure and board regulation of genetic counseling in Florida. Genetic counselors are graduates of master's or doctoral programs who provide confidential information and support to clients regarding genetic conditions or birth defects. They provide supportive care to patients with potential or actual genetic diseases, and they counsel patients concerning the origin, transmission, and development of hereditary characteristics related to birth abnormalities.

The Florida Department of Health (DOH) does not currently certify or license genetic counselors. National certification has been available since 1993. According to the department, there are currently 40 certified genetic counselors in Florida.

The bill provides legislative intent, definitions, licensure requirements, exemptions, fees, and grounds for discipline. It creates a seven-member Board of Genetic Counselors in the Department of Health and provides requirements for membership and appointment to the board, and rulemaking authority.

The Sunrise Act, codified in s. 11.62, F.S., requires the Legislature to review all legislation proposing regulation of a previously unregulated profession or occupation based on a showing of the following:

- 1) That there is substantial risk of harm to the public with no regulation;
- 2) That the skill 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; and
- 5) That the overall cost effectiveness and economic impact of the proposed regulation is favorable.

Section 456.025(3), F.S., requires each licensed health profession to ensure that license fees are adequate to cover all anticipated costs of licensure and maintain a reasonable cash balance. According to DOH, the profession is expected to operate at a deficit due to the small number of anticipated licensees. Total biennial expenses for an estimated 40 applicants in year 1, and 5 in year 2, are expected to be \$65,750. Biennial licensure and renewal fees for these 45 licensees will only provide an estimated \$13,500. To meet expected expenses, biennial fees for each licensee would have to exceed the \$200 limits established by the bill. The deficit would be covered by the Medical Quality Assurance Trust Fund from fees paid by other professions.

The effective date of the bill is July 1, 2004. According to DOH, this effective date does not provide the department sufficient time to adopt rules, forms, or update the practitioner database.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0479a.hc.doc
DATE: March 4, 2004

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|--|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a “no” above, please explain:

This bill creates a new licensure and regulatory program. The Department of Health would incur additional costs to implement this program.

B. EFFECT OF PROPOSED CHANGES:

The bill creates part XV, ch. 468, F.S., the “Genetic Counseling Practice Act,” providing for the regulation of genetic counselors within the Department of Health by a seven-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; and
- 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 s. 456.001, F.S., 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 seven members appointed by the Governor and confirmed by the Senate. Five 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, 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; and
- 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 Department of Health may 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 board is authorized to establish the following fees:

- Application--no greater than \$100;
- Initial licensure--no greater than \$200;
- Biennial renewal--no greater than \$200; and
- Inactive, delinquent, reactivation or voluntary inactive fees--no greater than \$100 each.

Sanctions

Criminal offenses are created 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.

Effective Date

The bill provides an effective date of July 1, 2004.

PRESENT SITUATION

Legislative History

Legislation requiring the licensure of genetic counselors in Florida was filed in 2002 and 2003. In 2003, SB 2222 was unanimously passed by the Health, Aging and Long-Term Care, and Governmental Oversight and Productivity Committees, but its companion, HB 1351, was not considered in the House. 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 they are faced with 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.

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.

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, over 1000 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 last year, 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% and 70% of the physician cost.

National Certification

Genetic counselors currently achieve "Board Certification" by:

- 1) Completing an accredited training program;
- 2) Completing and documenting a minimum of 50 supervised clinical cases in a variety of genetic counseling clinic settings; and
- 3) 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.

Genetic counselor training programs grant a Master of Science or doctoral degree. There are 27 accredited genetic counseling training programs (seventeen fully accredited programs, eight new programs, and two 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. 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 s. 11.62, F.S., 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 skill 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; and
- (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, 2003.

Current Regulatory Framework for Health Professions

Chapter 456, F.S., 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 over 750,000 licensed health care practitioners. Each profession, except those regulated directly by the department, is represented by a board or council comprised of 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.

C. SECTION DIRECTORY:

Section 1. Creates ss. 468.901- 486.913, as Part XV of ch. 468, F.S., known as the "Genetic Counseling Practice Act," to establish regulation of genetic counselors.

Section 2. Amends s. 20.43(3)(g), F.S., to add 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., to redefine 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 July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Estimates provided by the Department of Health:

| <u>Estimated Revenue</u> | <u>1st Year</u> | <u>2nd Year</u> (Annualized/Recurring) |
|--------------------------------|-----------------|---|
| Licensure Fees | \$12,000 | \$1,500 |
| Total Estimated Revenue | \$12,000 | \$1,500 |

*See Fiscal Comments below.

2. Expenditures:

Estimates provided by the Department of Health:

| <u>Estimated Expenditures</u> | <u>1st Year</u> | <u>2nd Year</u> (Annualized/Recurring) |
|---|-----------------|---|
| Salaries | * | * |
| Other Personal Services | \$1,400 | \$350 |
| Board Member Compensation | | |
| Expense | | |
| Board Member travel, per diem, and lodging | \$11,200 | \$2,800 |
| Operating Capital Outlay | | |
| Total Estimated Expenditures | \$12,600 | \$3,150 |

*Because this is a small profession, salaries would be included in expenditures "allocated" to the profession based on workload and other costs for handling of applications, investigations, prosecutions, administrative hearings, the impaired practitioner program, etc. The department estimates that these costs will represent approximately \$25,000 per year.

*See Fiscal Comments below.

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:

State Revenues:

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. The department assumes that 40 genetic counselors will apply for Florida certification during fiscal year 2004-2005 (\$100 application fee plus \$200 initial licensure fee) and assumes that only 5 applicants will apply during fiscal year 2005-2006.

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 \$200; biennial renewal, no greater than \$200; and inactive, delinquent, reactivation, or voluntary inactive licensure status, all of which may be no greater than \$100.

State Expenditures:

The Department of Health will incur costs to implement the regulation of genetic counseling. Costs of licensure oversight generally include such costs as reviewing applications for licensure, investigating complaints, handling discipline, and supporting board meetings, policy, and rulemaking. These costs vary by profession depending on the size of the profession and whether it has a separate board.

This bill establishes the Board of Genetic Counselors composed of seven board members. The Department of Health estimates that in year one, there will be 4 meetings in which board members would be entitled to \$50 compensation and an average reimbursement of \$400 travel, per diem, and hotel expenses. During fiscal year 2005-2006, the department estimates that the board will hold at least one meeting.

On top of 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, etc. Each quarter, the department collects statistics from a variety of sources to fairly and appropriately allocate expenditures.

According to the department, when it is required to regulate a small profession, revenues associated with that profession are usually insufficient to cover direct and allocated expenditures. For professions that are in a chronic deficit status, expenditures that exceed revenue are subsidized by the MQA Trust Fund cash balance. According to the department, professions in a surplus status argue that they are subsidizing the deficit professions.

Based on the fiscal information provided by the department, the biennial expenditures of \$15,750 for the board, and approximately \$50,000 for staff and other expenses for handling applications, establishing the practitioner database, etc., would total \$65,750. This would not be met by the expected revenue of \$13,500. To meet expected expenses, the estimated 45 licensees (40 in year 1 and 5 in year 2) would have to pay biennial fees of approximately \$1,461 each. This exceeds the \$200 caps on fees established by the bill.

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to 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 revenues.

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 s. 456.004, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the July 1, 2004, effective date of the bill will not allow the department sufficient time to adopt rules, forms, or update the practitioner data base.

The Department of Health is concerned that the fee caps established in the bill are too low to provide sufficient revenue to cover the costs of licensure and regulation of the profession.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 4, 2004, the Subcommittee on Health Standards adopted the following amendment to the bill and then reported the bill favorably to the Committee on Health Care as amended:

Amendment #1 – A strike-all amendment that provides for cost-effective administration of licensure by reducing the size of the board from 7 to 5 members, providing for licensure fees up to \$600, and delaying implementation until October 1, 2004. The strike-all amendment incorporates an amendment to provide that the board “shall” rather than “may” establish rules regarding continuing education.