

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/CS/CS/CS/SB 506

SPONSOR: Appropriations Subcommittee on Health and Human Services; Finance and Taxation Committee; Governmental Oversight and Productivity Committee; Health, Aging, and Long-Term Care Committee, and Senator Cowin

SUBJECT: Genetic Counselors

DATE: March 4, 2004

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Fav/CS</u>
2.	<u>Krasovsky</u>	<u>Krasovsky</u>	<u>MS</u>	<u>Favorable</u>
3.	<u>White</u>	<u>Wilson</u>	<u>GO</u>	<u>Fav/CS</u>
4.	<u>Keating</u>	<u>Johansen</u>	<u>FT</u>	<u>Fav/CS</u>
5.	<u>Peters</u>	<u>Belcher</u>	<u>AHS</u>	<u>Fav/CS</u>
6.	_____	_____	<u>AP</u>	_____

I. Summary:

The Committee Substitute for Committee Substitute for Committee Substitute for Senate Bill 506 provides for the regulation of genetic counseling in Florida by the Board of Genetic Counselors in the Department of Health. In providing for the regulation of genetic counseling, the bill provides legislative intent, definitions, requirements for licensure, exemptions, rulemaking authority for the newly-created 5-member Board of Genetic Counselors, requirements for membership and appointment to the board, and fees. The bill establishes criminal penalties for certain prohibited acts, including the making of false or fraudulent statements to the Board of Genetic Counselors, the practice of genetic counseling without the required licensure or exemption thereto, and the use of the title "genetic counselor" without a license. The bill establishes grounds for which genetic counselors may be disciplined for failure to adhere to specified standards of practice by their board. The bill redefines "health care practitioner" in chapter 456, F.S., the general regulatory provisions for health care professions under the Department of Health, to include genetic counselors.

This bill creates part XV of chapter 468, Florida Statutes, which includes sections 468.901, 468.902, 468.903, 468.904, 468.905, 468.906, 468.907, 468.908, 468.909, 468.911, 468.912, and 468.913, F.S.

This bill amends sections 20.43 and 456.001, F.S.

II. Present Situation:

Genetic counselors offer supportive care to patients with potential or actual genetic diseases, and counsel patients concerning the origin, transmission, and development of hereditary characteristics that have a relationship to birth abnormalities. Genetic counselors provide confidential information to clients about sensitive and emotional issues involving genetic conditions or birth defects or the potential for such things to occur. Genetic counselors work closely with obstetricians and other health care practitioners who provide maternal and family medicine.

Since 1993, national certification has been available for genetic counselors. 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. The certifying examination was offered by the ABGC for the first time in 1993. Prior to the establishment of the ABGC, certification in this specialty was offered by the American Board of Medical Genetics (ABMG). The 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.

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:

- That substantial risk of harm to the public is a risk of no regulation which is recognizable and not remote;
- That the skill the profession requires are specialized and readily measurable;
- That other forms of regulation do not or cannot adequately protect the public; and
- 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 that is proposed to have jurisdiction over the regulation and the legislative committees of reference information concerning the effect of proposed legislation to initially regulate a previously unregulated profession on the agency's resources to implement and enforce the regulation.

A sunrise questionnaire has not been completed. The proponents of the regulation, members of the National Society of Genetic Counseling, informally have indicated that approximately 50 to 60 genetic counselors are in Florida and estimate that approximately 37 of that number are certified by the ABMG or ABGC. The proponents indicated that the average annual salary of genetic counselors ranges from \$35,000 to \$60,000. The Department of Health indicates that

internationally there are approximately 2,000 genetic counselors and 1,410 are certified genetic counselors, 37 of whom are in Florida.

Chapter 456, F.S., provides the general regulatory provisions for health care professions within the Division of Medical Quality Assurance in the Department of Health. Section 456.001, F.S., defines the term, "health care practitioner" to include the professions regulated under the Division of Medical Quality Assurance within the Department of Health. The organization of the Department of Health is created in s. 20.43, F.S., including the Division of Medical Quality Assurance which is responsible for various boards and professions established within the division.

III. Effect of Proposed Changes:

Section 1. 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 five-member board. Section 468.902, F.S., provides Legislative intent 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. In addition, the bill specifies that this act does not apply to counselors who do not identify or advertise themselves as genetic counselors, and who do not provide genetic risk assessment, diagnosis and interpretation of family history and genetic test results.

Section 468.903, F.S., provides definitions. "Genetic counselor" is a person licensed under this part to practice genetic counseling. "Practice of genetic counseling" is, for remuneration, the communication process that deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family, including the provision of services to help an individual or family:

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

Section 468.904, F.S., provides that a person may not practice genetic counseling or hold himself or herself out as a genetic counselor or as being able to practice genetic counseling or to render genetic counseling services in Florida unless he or she is licensed under this act.

Section 468.905, F.S., provides exemptions to the licensure requirements to public health or military officers while acting within the scope of their military or public health responsibilities, and to health care practitioners as defined in s. 456.001, F.S., who may perform genetic counseling in a manner that is consistent with the health care practitioner's training and licensure.

Section 468.906, F.S., creates the Board of Genetic Counselors within the Department of Health and must consist 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 residents of the state who are not, and have never been, licensed as a genetic counselor or members of any closely related profession. The terms of the members of the board are staggered. All provisions of ch. 456, F.S., relating to the board apply. These provisions include general regulatory provisions for health care professions within the Department of Health.

Section 468.907, F.S., authorize the board to adopt rules to implement its duties, including rules relating to standards of practice for genetic counselors.

Section 468.908, F.S., provides for the licensing of genetic counselors. To become licensed to practice genetic counseling in Florida, in addition to paying required fees and completing an application, an applicant must:

- Be of good moral character;
- Provide documentation of having completed:
 - 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
- Have passed the examination for certification as a genetic counselor by:
 - The American Board of Genetic Counseling or the American Board of Medical Genetics; or
 - 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 and has obtained active candidate status establishing eligibility to sit for the next available certification exam administered by the American Board of Genetic Counseling.

Section 468.909, F.S., requires the Department of Health to renew a genetic counselor's license upon receipt of the renewal application and fee set by the board which may not exceed \$600. The bill also grants the Board of Genetic Counselors specific rulemaking authority to prescribe continuing education requirements and approve course criteria for license renewal. The board must establish a procedure for approving continuing education courses and providers and may set a fee for continuing education course and provider approval.

Section 468.911 authorizes the board to establish the following fees:

- Application fee, no greater than \$100;
- Initial licensure fee, no greater than \$600;
- Biennial renewal fee, no greater than \$600; and
- Inactive, delinquent, reactivation, or voluntary inactive fee licensure status, all of which may be no greater than \$100.

The board must establish fees at a level which do not exceed the statutory fee cap, and which are adequate to ensure the continued operation of the regulatory program for genetic counselors.

Section 468.912, F.S., creates criminal offenses for the following:

- Making false or fraudulent statements in any application, affidavit, or statement presented to the board;
- Practicing genetic counseling without a license; and
- Using the title genetic counselor or other similar designation unless that person is licensed or exempt from the licensing requirements for genetic counseling.

A person who violates the prohibitions created in the bill is guilty of a second degree misdemeanor punishable by jail time up to 60 days and the imposition of a fine up to \$500.

Section 468.913, F.S., provides grounds for which a genetic counselor may be subject to discipline for violating practice standards. The board may deny licensure or impose any of the penalties in s. 456.072(2), F.S., for violating the practice standards or any provision of s. 456.072, F.S.

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 October 1, 2004.

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, s. 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 Art. I, s. 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. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

The Board of Genetic Counselors is authorized to establish the following fees for the regulation of genetic counseling: application fee - no greater than \$100; initial licensure fee - no greater than \$600; biennial renewal fee - no greater than \$600; and inactive, delinquent, reactivation, or voluntary inactive fee licensure status, all of which may be no greater than \$100.

Based on the Department of Health's estimate that 40 genetic counselors will apply for licensure in fiscal year 2004-2005 and 5 genetic counselors in fiscal year 2005-2006, the fiscal impact would be \$28,000 (40 x \$700) in fiscal year 2004-2005 and \$3,500 (5 x \$700) in fiscal year 2005-2006.

B. Private Sector Impact:

Persons seeking to practice genetic counseling in Florida will incur the expenses to meet the licensure requirements established in the bill.

C. Government Sector Impact:

The Department of Health will incur costs to implement the regulation of genetic counseling. This bill establishes the Board of Genetic Counselors composed of 7 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. Total costs are \$12,600 in FY 2004-05 and \$3,150 in FY 2005-06. The department assumes that 40 genetic counselors will apply for Florida certification during fiscal year 2004-2005 (\$100 application fee plus \$600 initial licensure fee) and assumes that only 5 applicants will apply during fiscal year 2005-2006.

The Department of Health's estimated expenses are direct expenditures. All boards and councils also incur allocated expenses that cannot be direct charged. The department reports that examples of these costs include disciplinary costs, and the practitioner profile data base costs. While the amount of allocated charges is indeterminate, it could range from \$2,500 to \$25,000 annually, according to the department. The Department of Health reports that it is certain that this board would operate in a deficit posture due to the small licensure base.

VI. Technical Deficiencies:

The effective date of July 1, 2004 does not provide the Department of Health with enough time to make board appointments. An October 1, 2004 effective date would be preferable.

VII. Related Issues:

Chapters of law providing for the licensure of physicians, chiropractors, and dieticians include an exemption indicating that the chapter does not apply to the practice of the religious tenets of any church.¹ This bill does not include this provision.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

¹ See Sections 458.303(1)(g), 459.002(1)(g), 460.402(4), and 468.505(3), F.S.