

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1233 Genetic Counseling Patient Protection Act

SPONSOR(S): Professions & Public Health Subcommittee, Silvers

TIED BILLS: HB 1235 **IDEN./SIM. BILLS:** SB 1770

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	14 Y, 0 N, As CS	Morris	McElroy
2) Health Care Appropriations Subcommittee		Mielke	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. The MQA works in conjunction with 22 boards and four councils to license and regulate seven types of health facilities and more than 40 health care professions. Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory authority and licensure authority for MQA, including the discipline of practitioners.

Genetic counselors provide individuals information about how genetic conditions might affect them or their families. Genetic counselors collect personal and family history and use such information to determine how likely it is that an individual or his or her family member has a genetic condition. Genetic counselors are not licensed or regulated in this state.

CS/HB 1233 creates the "Genetic Counseling Patient Protection Act," requiring DOH to regulate and license genetic counselors. The bill:

- Creates requirements for initial licensure and renewal for genetic counselors;
- Establishes the scope of practice for licensed genetic counselors;
- Authorizes DOH to adopt rules regarding continuing education requirements;
- Subjects genetic counselors to disciplinary action if they commit specified prohibited acts;
- Authorizes DOH to deny an application for licensure or impose penalties on a licensee who commits specified prohibited acts; and
- Exempts active duty commissioned medical officers of the United States Armed Forces or Public Health Service and licensed health care practitioners from the requirements of the genetic counselor practice act.

The bill also makes technical and conforming changes.

The bill has a significant, negative fiscal impact on DOH. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2021.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Health Care Professional Licensure

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. MQA works in conjunction with 22 boards and 4 councils to license and regulate 7 types of health care facilities and more than 40 health care professions.¹ Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for MQA. MQA is statutorily responsible for the following boards and professions established within the division:²

- The Board of Acupuncture, created under ch. 457, F.S.;
- The Board of Medicine, created under ch. 458, F.S.;
- The Board of Osteopathic Medicine, created under ch. 459, F.S.;
- The Board of Chiropractic Medicine, created under ch. 460, F.S.;
- The Board of Podiatric Medicine, created under ch. 461, F.S.;
- Naturopathy, as provided under ch. 462, F.S.;
- The Board of Optometry, created under ch. 463, F.S.;
- The Board of Nursing, created under part I of ch. 464, F.S.;
- Nursing assistants, as provided under part II of ch. 464, F.S.;
- The Board of Pharmacy, created under ch. 465, F.S.;
- The Board of Dentistry, created under ch. 466, F.S.;
- Midwifery, as provided under ch. 467, F.S.;
- The Board of Speech-Language Pathology and Audiology, created under part I of ch. 468, F.S.;
- The Board of Nursing Home Administrators, created under part II of ch. 468, F.S.;
- The Board of Occupational Therapy, created under part III of ch. 468, F.S.;
- Respiratory therapy, as provided under part V of ch. 468, F.S.;
- Dietetics and nutrition practice, as provided under part X of ch. 468, F.S.;
- The Board of Athletic Training, created under part XIII of ch. 468, F.S.;
- The Board of Orthotists and Prosthetists, created under part XIV of ch. 468, F.S.;
- Electrolysis, as provided under ch. 478, F.S.;
- The Board of Massage Therapy, created under ch. 480, F.S.;
- The Board of Clinical Laboratory Personnel, created under part III of ch. 483, F.S.;
- Medical physicists, as provided under part IV of ch. 483, F.S.;
- The Board of Opticianry, created under part I of ch. 484, F.S.;
- The Board of Hearing Aid Specialists, created under part II of ch. 484, F.S.;
- The Board of Physical Therapy Practice, created under ch. 486, F.S.;
- The Board of Psychology, created under ch. 490, F.S.;
- School psychologists, as provided under ch. 490, F.S.;
- The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under ch. 491, F.S.; and
- Emergency medical technicians and paramedics, as provided under part III of ch. 401, F.S.

Genetic Counseling

¹ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, p. 6, <http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/documents/2019-2020-annual-report.pdf> (last visited on March 26, 2021).

² Id.

Advances in genetic technology and research have increased the amount of information available to individuals and providers and increased the demand for genetic services, including genetic testing, diagnosis and interpretation of test results, and genetic counseling.³ Genetic test results can help diagnose, confirm, or indicate increased risk for developing a particular condition, which genetic counseling can help explain the results and available treatment options.

Genetic counseling gives individuals information about how genetic conditions might affect them or their families. Genetic counselors collect personal and family history and use such information to determine how likely it is that an individual or his or her family member has a genetic condition. Based on such information, a genetic counselor helps an individual determine if a genetic test is suitable. Genetic counseling after genetic testing can help an individual better understand his or her test results and treatment options.⁴

Individuals seek genetic counseling for multiple reasons, including to:⁵

- Address prenatal concerns about factors that might affect a baby during infancy, including genetic conditions and birth defects;
- Address concerns if a child is showing signs and symptoms of a genetic disorder, including abnormal newborn screening results, intellectual or developmental disabilities, or birth defects;
- Determine if an individual is at risk of being affected by a health condition, including hereditary breast and ovarian cancer, muscular dystrophy, Huntington’s disease, and sickle cell disease.

Genetic counselors who wish to become certified must pass a certification examination issued by the American Board of Genetic Counseling (ABGC).⁶ The primary qualification to sit for the certification examination is a master’s degree in genetic counseling from a program accredited by the Accreditation Council for Genetic Counseling.⁷ States currently issuing a genetic counselor license require individuals to pass the ABGC certification examination.⁸

Genetic counselors primarily practice in hospital settings and can work in all medical specialties or practice in one specialty area, such as pediatrics, oncology, or cardiology.⁹ They assess individuals or families with or at risk for genetic conditions and provide counseling and education on test results. Genetic counselors are not physicians; they typically work in conjunction with medical geneticists to provide genetic services.¹⁰ Medical geneticists will order genetic testing and interpret the results and a genetic counselor will provide further education on the results and how they may affect an individual or their family.¹¹

Twenty-nine states require licensure for genetic counselors.¹² Florida does not require licensure and there are approximately 127 genetic counselors providing services in this state.¹³

Sunrise Act

³ United States Government Accountability Office, Report to Congressional Committees: Genetic Services – Information on Genetic Counselor and Medical Geneticist Workforces (July 2020), <https://www.gao.gov/assets/gao-20-593.pdf> (last visited March 26, 2021).

⁴ Centers for Disease Control and Prevention, *Genetic Counseling*, https://www.cdc.gov/genomics/gtesting/genetic_counseling.htm (last visited March 26, 2021).

⁵ Id.

⁶ American Board of Genetic Counseling, Inc., *Certification Qualifications*, <https://www.abgc.net/becoming-certified/do-i-qualify/> (last visited March 26, 2021). Certification is valid for 5 years, after which time the genetic counselor must seek recertification.

The University of South Florida has the only certified genetic counseling training program in Florida.

⁷ Id.

⁸ Id.

⁹ Id.

¹⁰ Medical geneticists are physicians who specialist in medical genetics and conduct genetic testing and provide diagnoses.

¹¹ *Supra*, note 6.

¹² National Society of Genetic Counselors, *States Issuing Licenses for Genetic Counselors*, <https://www.nsgc.org/Policy-Research-and-Publications/State-Licensure-for-Genetic-Counselors/States-Issuing-Licenses> (last visited March 26, 2021). States requiring licensure of generic counselors include: Alabama, Arkansas, California, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Utah, Virginia, and Washington.

¹³ Department of Health, Agency Analysis of 2021 House Bill 1233 (March 22, 2021).

Generally, a sunrise review is a formal process where a legislature scrutinizes legislation proposing to regulate an unregulated profession or occupation by requiring a cost-benefit analysis before the legislation is enacted.¹⁴ The Sunrise Act requires the Legislature to consider certain factors before determining whether to regulate an unregulated profession or occupation.¹⁵ Proponents of regulation must file information about the regulation's potential impacts, costs, and benefits upon request.¹⁶

Section 11.62, F.S., is Florida's sunrise review, which is called the Sunrise Act. The Sunrise Act states that regulation should not be adopted unless it is:¹⁷

- Necessary to protect the public health, safety, or welfare from significant and discernible harm or damage;
- Exercised only to the extent necessary to prevent the harm; and
- Limited so as not to unnecessarily restrict entry into the practice of the profession or adversely affect public access to the professional services.

In determining whether to regulate a profession or occupation, the Sunrise Act requires the Legislature to consider the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

Genetic Counselor Sunrise Act Questionnaire

A Sunrise Act questionnaire has been completed by The Florida Association of Genetic Counselors (FLAGC).¹⁸ FLAGC is seeking licensure and regulation of genetic counselors to protect the health, safety, and welfare of the public.¹⁹ Florida does not license or regulate genetic counselors.

¹⁴ National Conference of State Legislatures, Improving Occupational Licensing with Sunrise and Sunset Review Acts, <https://www.ncsl.org/research/labor-and-employment/improving-occupational-licensing-with-sunrise-and-sunset-reviews.aspx> (last visited March 26, 2021).

¹⁵ S. 11.62, F.S.

¹⁶ S. 11.62(4), F.S.

¹⁷ S. 11.62(2), F.S.

¹⁸ The Florida Association of Genetic Counselors, Sunrise Review for Proposed Licensing of Genetic Counselors (on file with the Professions and Public Health Subcommittee staff).

¹⁹ Id.

Effect of the Bill

CS/HB 1233 creates the “Genetic Counseling Patient Protection Act,” adding genetic counselors to the list of health care practitioners requiring licensing and regulation by DOH.

The bill establishes the scope of practice for genetic counselors, which is to advise individuals or families affected by or at risk of genetic disorders. Genetic counselors may advise an individual or a family affected by or at risk of genetic disorders, including:

- Evaluating individual and family medical histories to determine risk for genetic or medical conditions and diseases;
- Discussing health factors and risk management for genetic or medical conditions and diseases with patients;
- Ordering genetic laboratory tests and diagnostic studies;
- Evaluating laboratory test results and diagnostic studies against individual and family medical history to assess risk factors for genetic or medical conditions and diseases;
- Explaining clinical implications of genetic laboratory tests and diagnostic studies results to patients;
- Evaluating the individual or family and providing client centered counseling and guidance;
- Using community resources that provide medical, educational, financial, and psychosocial support and advocacy;
- Providing written documentation of medical, genetic, and counseling information for individuals, families, and health care professionals; and
- Referring individuals to a physician for diagnosis and treatment.

The bill creates requirements for licensure as a genetic counselor and requires DOH to issue a license, valid for two years, to an applicant who:

- Submits an application on a form approved by DOH;
- Is of good moral character;
- Has earned a:
 - Master’s degree from a genetic counseling program or an equivalent program as determined by the ABGC Counseling or its successor or equivalent; or
 - Doctoral degree from a medical genetics program accredited by the American Board of Genetics and Genomics or the Canadian College of Medical Geneticists.
- Passes the examination for certification as:
 - A genetic counselor by the ABGC, the American Board of Genetics and Genomics, or the Canadian Association of Genetic Counselors; or
 - A medical or clinical geneticist by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.

The bill authorizes DOH to issue a temporary license for up to two years to applicants who meet all the requirements for licensure, except for the examination requirement if the applicant is eligible to sit for the next available certification examination.

The bill requires DOH to renew the license of a genetic counselor upon receipt of a renewal application. The bill also requires DOH to adopt rules on continuing education requirements consistent with the ABGC.

The bill prohibits a person from:

- Making a false or fraudulent statement in any application, affidavit, or statement presented to DOH;
- Practicing genetic counseling, holding himself or herself out as a genetic counselor, or providing genetic counseling services without obtaining a license from DOH; and

- Using the title “genetic counselor” or any other title, designation, words, letters, or abbreviations which indicate a person is authorized to practice genetic counseling unless such person holds a valid license or is exempt from such licensure.

The bill makes it a second degree misdemeanor to violate any of the above prohibitions, punishable by a fine of up to \$500 and imprisonment of up to 60 days. The bill authorizes DOH to discipline a genetic counselor, or deny an application for licensure as a genetic counselor, if an applicant or licensee:

- Fraudulently attempts to obtain, obtains, or renews a license as a genetic counselor;
- Has a license revoked, suspended, or otherwise acted against, including licensure denial, in another jurisdiction;
- Is convicted, found guilty of, or pleads no contest to a crime in any jurisdiction that directly related to the practice of genetic counseling, including violations of federal law;
- Makes or files a false report that the licensee knows is false;
- Intentionally or negligently fails to file a report required by state or federal law, or willfully impedes, obstructs, or induces another person to impede or obstruct such filing;
- Knowingly advertises genetic counseling services in a fraudulent, false, deceptive, or misleading manner;
- Violates a DOH-issued disciplinary order or fails to comply with a DOH-issued subpoena;
- Practices with a revoked, suspended, or inactive license;
- Commits gross or repeated malpractice, or fails to deliver genetic counseling services at an acceptable level of care;
- Displays unprofessional conduct, including failure to conform to minimum standards set by the practice act and DOH rule, including:
 - Practicing beyond the scope of practice of a genetic counselor;
 - Failing to refer a patient to a health care practitioner if the licensed genetic counselor is unwilling or unable to provide services;
 - Failing to maintain confidentiality; and
 - Financially exploiting the patient or his or her family.
- Violates the genetic counseling practice act.

The bill exempts active duty commissioned medical officers of the United States Armed Forces or the United States Public Health Service and health care practitioners licensed in this state, other than licensed genetic counselors, from the requirements of the genetic counseling practice act.

The bill makes conforming technical and conforming changes.

The bill provides an effective date of July 1, 2021.

B. SECTION DIRECTORY:

- Section 1:** Creates Part III of ch. 483, F.S., the “Genetic Counseling Patient Protection Act.”
- Section 2:** Amends s. 456.001, F.S., relating to definitions.
- Section 3:** Amends s. 20.43, F.S., relating to Department of Health.
- Section 4:** Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

HB 1235, linked to CS/HB 1233, authorizes an initial application fee of \$25 and an annual renewal fee of \$25 for genetic counselors seeking licensure. The total annual revenue DOH will receive from such fees is approximately \$3,175 based on there being 127 genetic counselors currently practicing in Florida.

2. Expenditures:

DOH will incur costs associated with rulemaking to implement the bill's provisions, developing the licensure application, and updating the LEIDS licensing system. Current resources are adequate to absorb these costs.²⁰

DOH will incur costs associated with the regulation and licensure of genetic counselors. DOH estimates 3 FTE and 1 OPS position will be required to implement the provisions of the bill.²¹ The below table summarizes the various functions and costs associated with the regulation and licensure of genetic counselors under the bill:

Function	FTE Request and Description	FTE	Salary Rate	Salary & Benefits	OPS Cost	Recurring Expenses/HR Transfer	Nonrecurring Expenses	Total for Function
Application Processing	Two Regulatory Specialist FTE and one OPS to analyze, approve or deny licensure applications, and update practitioner profiles	2.0	63,700	91,091	35,360	18,971	13,287	158,709
Enforcement and Investigations	One Investigation Specialist FTE to review complaints associated with unlicensed activity	1.0	32,708	46,772		16,004	4,429	67,205
Total:		3.0	96,408	137,863	35,360	34,975	17,716	225,914

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Genetic counselors will incur costs associated with obtaining licensure by DOH.

D. FISCAL COMMENTS:

None.

²⁰ Id.

²¹ *Supra*, note 13.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to implement its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 1, 2021, the Professions and Public Health Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Established the scope of practice for licensed genetic counselors;
- Authorized genetic counselor licenses to be valid for 2 years;
- Required licensure applicants to graduate from a master's program approved by the Accreditation Council of Genetic Counseling or its successor or equivalent; and
- Authorized DOH to issue a temporary license to applicants who meet certain requirements.

This analysis is drafted to the committee substitute as passed by the Professions and Public Health Subcommittee.