

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 Committee on Health Policy

BILL: CS/SB 1770

INTRODUCER: Health Policy Committee and Senator Jones

SUBJECT: Genetic Counseling

DATE: March 25, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto Van-Winkle	Brown	HP	Fav/CS
2.	_____	_____	AP	_____
3.	_____	_____	RC	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1770 creates a new licensed and regulated profession, genetic counseling, within the Department of Health (DOH), Division of Medical Quality Assurance (MQA), in part III of ch. 483, F.S., and authorizes the new practice act to be cited as the “Genetic Counseling Workforce Act.” The bill provides:

- Legislative intent and findings to establish a new profession;
- Definitions for:
 - Genetic counselor; and
 - Scope of practice of genetic counseling;
- Requirements for initial licensure, renewal, and continuing education (CE);
- Grounds for disciplinary action and penalties; and
- Exemptions from genetic counseling regulation for:
 - Commissioned medical officers of the United States Armed Forces or Public Health Service while on active duty; and
 - Health care practitioners as defined in s. 456.001, F.S., other than genetic counselors, who are practicing within the scope of their education, training, and licensure.

The bill amends s. 456.001, F.S., to include genetic counselors in the definition of a health care practitioner and makes a technical change to s. 20.43, F.S.

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

II. Present Situation:

Genetic Counselors

In 1971 the first class of master's degree genetic counselors graduated from Sarah Lawrence College in Bronxville, NY.¹

Since 2017, the University of South Florida (USF) has been the first and only accredited genetic counseling training program in Florida. The program includes a unique combination of training in medical genetics and genomics, public health, and communication and counseling skills. The genetic counseling degree is a comprehensive, 21-month, full-time program that consists of didactic and skill-based courses, multiple clinical rotations, and field experiences beginning in the first semester, independent learning opportunities, and a thesis research requirement. Upon successful completion of the program, students receive a master's of science in public health with a concentration in genetic counseling (MSPH-GC) and are eligible to sit for the national board certification exam that is administered by the American Board of Genetic Counseling (ABGC).

The program currently graduates five board-eligible genetic counselors each year. However, state licensure for the profession, if enacted, is expected to grow the program by attracting more genetic counselors to the state who can provide supervision for clinical training. USF reported receiving 18-to-20 times more applicants than the program can accommodate.²

Genetic counselors are not doctors but they may be part of the genetic health care team. They meet with individuals or families before or after genetic testing. They specialize in prenatal, pediatric, oncology, neurology, ophthalmology, psychiatry, and many other areas. They work in research, education, industry, marketing, and many other roles across the health care and genetics fields.³

Genetic counselors help patients understand:⁴

- The genetic risks based on family history;
- The genetic risks for certain diseases or cancer;
- Whether genetic testing might be right for the patient; and
- What the results of genetic tests may mean for the patient and his or her family.

With expertise in counseling, genetic counselors can also provide emotional support as patients and family make decisions and empower those individuals with information for their overall health care.⁵

¹ National Society of Genetic Counselors, *Our History*, available at <https://www.nsgc.org/About/About-NSGC> (last visited Mar. 22, 2021).

² University of South Florida, USF Health, College of Public Health, Graduate Admissions, *MSPH with a Concentration in Genetic Counseling* available at <https://health.usf.edu/publichealth/apply/graduate-admissions/genetic-counseling> (last visited Mar. 22, 2021).

³ National Society of Genetic Counselors, *Who Are Genetic Counselors?* available at <https://www.aboutgeneticcounselors.org/Who-Are-Genetic-Counselors/Who-Are-Genetic-Counselors> (last visited Mar. 22, 2021).

⁴ *Id.*

⁵ *Id.*

As of October 2020, according to the National Society of Genetic Counselors (NSGC), 26 states now license genetic counselors.⁶

Regulation of Health Care Professions

The DOH, Division of MQA, is responsible for licensing and regulating health care practitioners in order to preserve the health, safety, and welfare of the public.⁷ General licensing provisions applicable to all health care practitioners are contained in ch. 456, F.S., which also sets out in detail the regulatory policy framework. Specifically, regulation occurs when:⁸

- An unregulated practice can harm or endanger the health, safety, and welfare of the public;
- The potential for harm outweighs the potentially anticompetitive effect of the regulation;
- The public is not adequately protected by other means, of other statutes, federal law, or local ordinances; or
- Less restrictive means of regulation are not available.

The MQA has responsibility for:

- Licensing health care practitioners and certain facilities and businesses;
- Enforcing health care practitioner standards; and
- Providing licensure and disciplinary information to enable health care consumers to make more informed health care decisions.

Regulation of some professions occurs under the purview of a board or council of the DOH. A board is a statutorily-created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.⁹ In general, boards are responsible for approving or denying applications for licensure, establishing continuing education requirements, and disciplining practitioners for violations of their applicable practice act.¹⁰ Currently, the MQA licenses and regulates seven types of health care facilities and more than 200 license types in over 40 professions, while partnering with 22 boards and four councils.¹¹

Florida does not license or regulate genetic counselors.

Professional Regulation and The Florida Sunrise Act

Section 11.62, F.S., “The Sunrise Act,” sets forth legislative policy and minimum requirements for legislative review of bills proposing regulation of an unregulated occupation. In general, the Sunrise Act states that the regulation of an occupation or profession should not occur unless it is:

⁶ National Society of Genetic Counselors, *States Issuing Licenses for Genetic Counselors*, available at <https://www.nsgc.org/Policy-Research-and-Publications/State-Licensure-for-Genetic-Counselors/States-Issuing-Licenses> (last visited Mar. 22, 2021).

⁷ Section 20.43(1)(g), F.S.

⁸ Section 456.003(2), F.S.

⁹ Section 456.001(1), F.S.

¹⁰ *Id.*

¹¹ See Florida Department of Health, Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, available at <http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/documents/2019-2020-annual-report.pdf> (last visited Mar. 22, 2021).

- 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 occupation or profession or adversely affect public access to the professional services.

The Sunrise Act directs the Legislature to consider the following factors when determining whether to regulate a profession:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare;
- Whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training;
- Whether the skill or training is readily measurable or quantifiable so that an examination, or training requirements, would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will place an unreasonable burden on job creation or job retention in the state; or
- Whether 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 indirect costs to consumers, will be favorable.

The Sunrise Act also requires the proponents of the legislation to provide detailed information regarding the need and potential impact of the regulation. The Sunrise Questionnaire is used for that purpose.¹² The Sunrise Act requires the governmental agency that will be responsible for its implementation to also assess the cost of implementation, the technical sufficiency of the proposal, and whether alternatives to regulation exist.

In determining whether to recommend regulation, the legislative committee reviewing the proposal is directed to assess whether the proposed regulation is:

- Justified based on the statutory criteria and the information provided by both the proponents of regulation and the agency responsible for its implementation;
- The least restrictive and most cost-effective regulatory scheme necessary to protect the public; and
- Technically sufficient and consistent with the regulation of other professions under existing law.

Summary of the Florida Sunrise Act Questionnaire Responses

The Florida Association of Genetic Counselors (FLAGC) represents board-certified and board-eligible genetic counselors in the state of Florida. It is a state chapter of the national organization that represents genetic counselors, the National Society of Genetic Counselors or NSGC.

¹² A Sunrise Questionnaire has been provided by the proponent of the new regulation pursuant to s. 11.62(4), F.S. SB 1770 and has been submitted by The Florida Association of Genetic Counselors, *Sunrise Review for Proposed Licensing of Genetic Counselors* (on file with the Senate Committee on Health Policy).

According to FLAGC, there are currently 130 genetic counselors registered in the state of Florida certified by the American Board of Genetic Counseling. All 130 ABGC-certified genetic counselors would be subject to regulation under the bill.¹³

The FLAGC has provided to the Senate Health Policy Committee responses to the factors listed in s. 11.62(3)-(4), F.S., as evidence for the Legislature is to consider in determining whether licensure of genetic counselors is necessary to protect the health, safety, and welfare of the public. A summary of the responses follows.

Substantial Harm or Endangerment

The FLAGC's response to the substantial harm and endangerment factor is that patient harm from inadequate genetic counseling services is well-documented in published literature and patient testimonials but concedes that there is a lack of documented cases of harm to patients in the state of Florida. There is currently no state mechanism for individual patients or their providers to "look up a license" to see if the person offering or providing genetic counseling services is, in fact, appropriately trained and bound by professional standards.¹⁴

Measurability of Specialized Skill or Training

According to the FLAGC, genetic counseling is a profession that requires a large amount of measurable specialized skills and training. Genetic counseling requires extensive post-graduate training in the specialized fields of genetic medicine and psychosocial counseling, including:

- Interpretation of information about DNA variants and disorders.
- Discussing recurrence risks.
- Providing case-management and psychological support services.
- Interpreting complex genetic assays.
- Counseling clients regarding test results.

The FLAGC also points to the education genetic counselor requires to become eligible to take the ABGC certification examination, which is a minimum of 21 months or two academic years leading to a master's degree, followed by a requirement for the individual to take the ABGC Board Certification Examination, consisting of 200 multiple-choice questions based on the most recent ABGC Practice Analysis and which is conducted every three to five years.¹⁵

Unreasonable Effect on Job Creation or Retention

The FLAGC contends that allowing state licensure of genetic counselors would help lift current barriers to job creation, job retention, and the ability for individuals pursuing a career in genetic counseling to find employment while remaining in the state of Florida and that, by helping to attract and retain genetic counselors, state licensure will also help create more in-state training opportunities and increase competition in the field. Licensed health care practitioners also may

¹³ The Florida Association of Genetic Counselors (FLAGC), *Sunrise Review for Proposed Licensing of Genetic Counselors*, (on file with the Senate Committee on Health Policy).

¹⁴ *Id.*

¹⁵ *Id.*

be reimbursed for their services at higher rates than unlicensed practitioners, according to the FLAGC.¹⁶

Can the Public Be Effectively Protected by Other Means?

The FLAGC indicates that while registration or certification, rather than licensure, are lower cost options, neither would provide the legal framework for genetic counselors to specify a scope of practice, mandate CEs, regulate and impose discipline that will better protect the public, and allow them to be credentialed to practice independent of a physician and be fully integrated into health care systems.¹⁷

Favorable Cost-effectiveness and Economic Impact

The FLAGC asserts that the economic benefit and cost savings realized through state licensure of genetic counselors would far outweighs the administrative burden and fiscal impact to the state. Providing state licensure to genetic counselors would help to increase the number of genetic counselors employed within the state of Florida, according to the FLAGC, which will:¹⁸

- Expand patient access to services;
- Reduce out-of-pocket costs;
- Reduce costs to health care systems; and
- Provide a positive economic benefit to the state by increasing workforce opportunities.

III. Effect of Proposed Changes:

The bill creates the new licensed profession of genetic counseling within the DOH in part III of ch. 483, F.S., and the practice act authorizes it to be cited as the “Genetic Counseling Workforce Act;”

The bill creates:

- Section 483.912, F.S., to provide Legislative findings and intent.
- Section 483.913, F.S., to define:
 - The “department” to mean the DOH;
 - “Genetic counselor” as a person licensed to practice genetic counseling;
 - The “scope of practice of genetic counseling” as the process of advising individuals or families affected by, or at risk of, genetic disorders, including:
- Obtaining and evaluating individual, family, and medical histories to determine genetic risk for genetic or medical conditions and diseases in a patient, his or her offspring, and other family members;
- Discussing the features, natural history, means of diagnosis, genetic and environmental factors, and management of risk for genetic or medical conditions and diseases;
- Identifying, ordering, and coordinating genetic laboratory tests and other diagnostic studies as appropriate for a genetic assessment;

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

- Integrating genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic or medical conditions and diseases;
- Explaining the clinical implications of genetic laboratory tests and other diagnostic studies and their results;
- Evaluating the client's or family's responses to the condition or risk of recurrence and providing client-centered counseling and anticipatory guidance;
- Identifying and using community resources that provide medical, educational, financial, and psychosocial support and advocacy;
- Providing written documentation of medical, genetic, and counseling information for families and health care professionals; and
- Referring patients to a physician for diagnosis and treatment.
- Section 483.914, F.S., to set out the licensure requirements for any person desiring to be licensed as a genetic counselor. The bill requires the applicant to apply to DOH on a DOH-approved form. The DOH must issue a license under the bill to an applicant if he or she provides documentation of all following:
 - Good moral character;
 - Having earned:
 - A master's degree from a genetic counseling training program or an equivalent program as determined by the Accreditation Council of Genetic Counseling or its successor or an equivalent entity; or
 - A doctoral degree from a medical genetics training program accredited by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists;
 - Having taken and passed one of the following certification examinations as a genetic counselor:
 - The American Board of Genetic Counseling, Inc.;
 - The American Board of Medical Genetics and Genomics;
 - The Canadian Association of Genetic Counsellors; or
- A medical or clinical geneticist examination from:
 - The American Board of Medical Genetics and Genomics; or
 - The Canadian College of Medical Geneticists.

The DOH may also issue a temporary license for up to two years to an applicant who meets all requirements for licensure except for the examination requirement and is eligible to sit for the certification examination administered by the American Board of Genetic Counseling, Inc.

- Section 483.915, F.S., to require:
 - The DOH to renew a genetic counselor's license upon receipt of a renewal application, without any additional requirements such as those normally associated with license renewal such as continuing education (CE) credits and the reporting of arrests or convictions since the last licensure; and
 - The DOH to adopt by rule CE requirements consistent with nationally accepted standards of the American Board of Genetic Counseling, Inc.
- Section 483.916, F.S., to:
 - Prohibit any person from:

- Making a false or fraudulent statement in any application, affidavit, or statement presented to the DOH;
- Practicing genetic counseling or holding himself or herself out as a genetic counselor or as being able to practice genetic counseling or to render genetic counseling services without a license issued under the bill unless exempt from licensure:
- Using the title “genetic counselor” or any other title, designation, words, letters, abbreviations, or device tending to indicate that the person is authorized to practice genetic counseling unless that person holds a current license as a genetic counselor or is exempt from licensure.
- Provide that any person who violates the above commits a second degree misdemeanor, punishable as provided in ss. 775.082 or 775.083, F.S.
- Section 483.917, F.S., to provide:
 - That the following acts constitute grounds for denial of licensure or disciplinary action, as specified in s. 456.072(2), F.S.:
 - Attempting to obtain, obtaining, or renewing a license by fraudulent misrepresentation;
 - Having a license revoked, suspended, or otherwise acted against, including the denial of licensure in another jurisdiction;
 - Being convicted or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the practice of genetic counseling, including a violation of federal laws or regulations regarding genetic counseling;
 - Making or filing a report or record that the licensee knows is false, intentionally or negligently failing to file a report or record required by state or federal law, willfully impeding or obstructing such filing, or inducing another person to impede or obstruct such filing. Such reports or records include only reports or records that are signed in a person’s capacity as a licensee;
 - Knowingly advertising services related to genetic counseling in a fraudulent, false, deceptive, or misleading manner;
 - Violating a previous order of the DOH entered in a disciplinary hearing or failing to comply with a subpoena issued by the DOH;
 - Practicing with a revoked, suspended, or inactive license;
 - Gross or repeated malpractice or the failure to deliver genetic counseling services with that level of care and skill which is recognized by a reasonably prudent licensed genetic counselor as being acceptable under similar conditions and circumstances;
 - Unprofessional conduct, including, but not limited to, any departure from or failure to conform to the minimal prevailing standards of acceptable practice, including, but not limited to, any of the following:
 - Practicing or offering to practice beyond the scope permitted by law or accepting and performing genetic counseling services the licensee knows, or has reason to know, he or she is not competent to perform;
 - Failing to refer a patient to a health care practitioner as defined in s. 456.001, F.S., if the licensee is unable or unwilling to provide genetic counseling services to the patient;
 - Failing to maintain the confidentiality of any information received under this part or failing to maintain the confidentiality of patient records pursuant to s. 456.057, unless such information or records are released by the patient or otherwise authorized or required by law to be released;

- Exercising influence on the patient or family in such a manner as to exploit the patient or family for financial gain;
- Violating this part or ch. 456, F.S., or any rules adopted pursuant thereto.
- That the DOH may enter an order denying licensure, or imposing penalties, against any applicant or licensee who is found guilty of violating any of the above or for s. 483.916, F.S.; and
- Section 483.918, F.S., to provide exemptions from the application of part III of ch. 893, F.S., for the following health care providers who also practice genetic counseling within the scope of practice of their professions:
 - Commissioned medical officers of the United States Armed Forces or the United States Public Health Service while on active duty or while acting within the scope of their military or public health responsibilities; and
 - Health care practitioners defined in s. 456.001, F.S., other than genetic counselors, who practice within the scope of their training, education, and licensure, and who are doing work consistent with that training, education, and licensure.

The bill makes two conforming and technical changes by:

- Amending s. 456.001, F.S., to include genetic counselors in the definition of health care practitioner; and
- Amending s. 20.43(8), F.S., to correct a technical error in the Florida Statutes relating to prior law under which health care professions were licensed and regulated by the Department of Business and Professional Regulation under ch. 455, F.S.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

CS/SB 1770 does not require applicants for genetic counseling licensure to pay a licensure or application fee. However, a separate bill, CS/SB 1772, provides that persons who apply to become licensed genetic counselors in Florida may be subject to an application fee of up to \$25, both for an initial application and for annual licensure renewal. *See* the staff analysis for CS/SB 1772 for further information on fees and the other provisions of that bill.

C. Government Sector Impact:

The DOH has not provided an estimated fiscal impact for the bill. The DOH will experience the costs of an increased workload to process applications for licensure and renewals and to regulate a new health care profession under the bill. The extent of these fiscal impacts is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.001 and 20.43.

This bill creates the following sections of the Florida Statutes: 483.911, 483.912, 483.913, 483.914, 483.915, 483.916, 483.917, and 483.918.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

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

CS by Health Policy on March 24, 2021:

The CS:

- Defines the genetic counselor's scope of practice more specifically than the underlying bill and adds the ability to order genetic testing;
- Specifies the duration the of initial licensure as two years;
- Corrects an error in the underlying bill related to the entity that actually accredits graduate programs; and

- Expands the time period in which those with temporary licenses must take the certification examination and removes the underlying bill's requirement for such an applicant to sit for the "next available" exam.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
