#### HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

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

SPONSOR(S): Health Care Appropriations Subcommittee and Professions & Public Health Subcommittee,

Silvers

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

FINAL HOUSE FLOOR ACTION: 116 Y's 1 N's GOVERNOR'S ACTION: Approved

### **SUMMARY ANALYSIS**

CS/CS/HB 1233 passed the House on April 28, 2021, as CS/SB 1770.

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/CS/HB 1233 creates the "Genetic Counseling Workforce 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 authorizes a genetic counselor to decline to participate in counseling that conflicts with the practitioner's moral or religious beliefs and prohibits DOH from disciplining such practitioner and making licensure contingent upon participation in such counseling. The bill prohibits a genetic counselor's refusal to provide services based on moral or religious conflict from being used as a basis for claim of damages if the practitioner informs the patient of the refusal to participate and and directs the patient to the DOH practitioner database.

The bill makes technical and conforming changes.

The bill appropriates \$41,535 in recurring funds and \$4,429 in nonrecurring funds from the Medical Quality Assurance Trust Fund to the DOH. The bill has no fiscal impact on local governments.

The bill was approved by the Governor on June 21, 2021, ch. 2021-133, L.O.F., the effective date of this bill is July 1, 2021.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1233z1.PPH.DOCX

### I. SUBSTANTIVE INFORMATION

#### A. EFFECT OF 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. 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:

- 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. *Military Health Care Practitioners*

An individual who serves or has served as a health care practitioner in the U.S. Armed Forces, U.S.

<sup>2</sup> ld.

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<sup>&</sup>lt;sup>1</sup> Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, p. 6, <a href="http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/\_documents/2019-2020-annual-report.pdf">http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/\_documents/2019-2020-annual-report.pdf</a> (last visited on April 30, 2021).

Reserve Forces, or the National Guard on active duty or has served on active duty with the U.S. Armed Forces as a health care practitioner in the U.S. Public Health Service, is eligible for licensure in Florida.<sup>3</sup> DOH is required to waive the application fee, licensure fee, and unlicensed fee for such applicants. The applicant will be issued a license to practice in Florida if the applicant submits a completed application, and:<sup>4</sup>

- Receives an honorable discharge within the 6 months before or after submission of the
- application;
- Holds an active, unencumbered license issued by another state, the District of Columbia, or a U.S. territory or possession, with no disciplinary action taken against it in the 5 years preceding the date of application;
- Is the spouse of a person serving on active duty and is a health care practitioner in a profession that does not require a license in another state, the applicant who is not licensed in another state if he or she provides:
  - Evidence of training or experience equivalent to the requirements for licensure in Florida; and
  - Proof of a passing score on the appropriate exam of a national or regional standards organization, if required for licensure in Florida.
- Attests that he or she is not, at the time of submission, the subject of a disciplinary proceeding
  in a jurisdiction in which he or she holds a license or by the U.S. Department of Defense for a
  reason related to the practice of the profession for which he or she is applying;
- Has actively practiced the profession for which he or she is applying for the 3 years preceding the date of application; and
- Submits to a background screening, if required for the profession for which he or she is applying, and does not have any disqualifying offenses.

# **Genetic Counseling**

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.<sup>5</sup> 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.<sup>6</sup>

<sup>3</sup> S. 456.024, F.S.

<sup>&</sup>lt;sup>4</sup> S. 456.024(3)(b), F.S.

<sup>&</sup>lt;sup>5</sup> United States Government Accountability Office, Report to Congressional Committees: *Genetic Services – Information on Genetic Counselor and Medical Geneticist Workforces* (July 2020), <a href="https://www.gao.gov/assets/gao-20-593.pdf">https://www.gao.gov/assets/gao-20-593.pdf</a> (last visited April 30, 2021). <sup>6</sup> Centers for Disease Control and Prevention, *Genetic Counseling*, <a href="https://www.cdc.gov/genomics/gtesting/genetic\_counseling.htm">https://www.cdc.gov/genomics/gtesting/genetic\_counseling.htm</a> (last visited April 30, 2021).

Individuals seek genetic counseling for multiple reasons, including to:7

- 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). 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. States currently issuing a genetic counselor license require individuals to pass the ABGC certification examination.<sup>8</sup>

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. 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. 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. Florida does not license or regulate genetic counselors.

# Conscience Clauses

Conscience clauses are laws that allow practitioners to refuse to provide services if such refusal is based on a conflict with the practitioner's moral or religious beliefs. Federal law protects such practitioners and prohibits recipients of certain federal funding from discriminating against practitioners who refuse to participate in services based on moral objections or religious beliefs. Common situations in which a practitioner may invoke a conscience clause include abortion, sterilization, assisted suicide, and euthanasia.

Florida law authorizes a physician to refuse to provide family planning services and contraception based on conflicts with his or her religious beliefs and prohibits the practitoner from being held liable for such refusal.<sup>16</sup>

<sup>&</sup>lt;sup>7</sup> Id.

<sup>&</sup>lt;sup>8</sup> American Board of Genetic Counseling, Inc., *Certification Qualifications*, <a href="https://www.abgc.net/becoming-certified/do-i-qualify/">https://www.abgc.net/becoming-certified/do-i-qualify/</a> (last visited April 30, 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.

<sup>9</sup> Id.

<sup>&</sup>lt;sup>10</sup> Medical geneticists are physicians who specialist in medical genetics and conduct genetic testing and provide diagnoses.

<sup>11</sup> Supra, note 8.

<sup>&</sup>lt;sup>12</sup> National Society of Genetic Counselors, *States Issuing Licenses for Genetic Counselors*, <a href="https://www.nsgc.org/Policy-Research-and-Publications/State-Licensure-for-Genetic-Counselors/States-Issuing-Licenses">https://www.nsgc.org/Policy-Research-and-Publications/State-Licensure-for-Genetic-Counselors/States-Issuing-Licenses</a> (last visited April 30, 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.

<sup>&</sup>lt;sup>13</sup> U.S. Department of Health and Human Services, *Conscious Protections for Health Care Providers*, https://www.bbs.gov/conscience/conscience-protections/index.html (last visited Aprl 30, 2021)

https://www.hhs.gov/conscience/conscience-protections/index.html (last visited Aprl 30, 2021).

14 Id. See 42 U.S.C § 300a-7 et seq., 42 U.S.C. § 238n, Patient Protection and Affordable Care Act sections 1303(b)(4) and 1553, and 42 U.S.C. § 18113.

<sup>&</sup>lt;sup>15</sup> Supra, note 13.

<sup>&</sup>lt;sup>16</sup> S. 381.0051(5), F.S.

### Professional Regulation and the Florida Sunrise Act

Section 456.003, F.S., specifies that health care professions be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions shall be regulated when:<sup>17</sup>

- Unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation;
- The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation; and
- Less restrictive means of regulation are not available.

Similarly, section 11.62, F.S., the "Sunrise Act," specifies that regulation should not be adopted unless it is:<sup>18</sup>

- 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.

The Sunrise Act requires the Legislature to consider certain factors before determining whether to regulate an unregulated profession or occupation.<sup>19</sup> Generally, a sunrise review is a formal process where by a legislature scrutinizes legislation proposing to regulate an unregulated profession or occupation by requiring a cost-benefit analysis before the legislation is enacted.<sup>20</sup> To enable this, the Act requires proponents of regulation to file information about the regulation's potential impacts, costs, and benefits upon request.<sup>21</sup>

#### Sunrise Act Criteria

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

- **Substantial Harm or Endangerment:** 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;
- Specialized Skill or Training, and Measurability: 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;
- Unreasonable Effect on Job Creation or Job Retention: 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;

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Effective Public Protection by Other Means: Whether the public is or can be effectively
protected by other means; and

<sup>&</sup>lt;sup>17</sup> S. 456.003, F.S.

<sup>&</sup>lt;sup>18</sup> S. 11.62(2), F.S.

<sup>&</sup>lt;sup>19</sup> S. 11.62, F.S.

<sup>&</sup>lt;sup>20</sup> National Conference of State Legislatures, Improving Occupational Licensing with Sunrise and Sunset Review Acts, <a href="https://www.ncsl.org/research/labor-and-employment/improving-occupational-licensing-with-sunrise-and-sunset-reviews.aspx">https://www.ncsl.org/research/labor-and-employment/improving-occupational-licensing-with-sunrise-and-sunset-reviews.aspx</a> (last visited April 30, 2021).

<sup>&</sup>lt;sup>21</sup> S. 11.62(4), F.S.

Favorable Cost-effectiveness and Economic Impact: 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

The Sunrise Act requires proponents of regulation to submit information documenting the need for the proposed regulation. A sunrise questionnaire was completed and submitted by the Florida Association of Genetic Counselors (FLAGC), which is a state chapter of the national organization that represents genetic counselors: the National Society of Genetic Counselors. According to the FLAGC, there are 130 ABGC-certified genetic counselors in Florida and 47 out-of-state genetic counselors who provide services to patients in Florida.<sup>22</sup> This means potentially at least 177 genetic counselors would require licensure under the bill. The FLAGC did not indicate how many genetic counselors support this legislation.

# Substantial Harm or Endangerment

According to the FLAGC, the harm from inadequate genetic counseling services is well-documented in publications and patient testimonials. However, the FLAGC does not provide or cite formal studies or surveys documenting such harm. Instead, the FLAGC provides personal anecdotes, a minority of which are from Florida, such as misdiagnosis and pregnancy terminations based on genetic testing results containing variants of uncertain significance, which may be interpreted by physicians as disease causing. The FLAGC notes that there is a lack of documented cases of harm to patients in Florida as no mechanism for lodging complaints about inappropriate genetic counseling exists.<sup>23</sup>

### Specialized Skill or Training, and Measurability

Genetic counseling is a specialized field in which genetic counselors are skilled in genetic risk assessment, client education, interpersonal communication, and counseling to provide services to clients and their families for diverse sets of genetic disorders.<sup>24</sup> Genetic counselors may focus their work in specialty areas, such as cardiovascular health, psychiatric health, and cancer.<sup>25</sup> ABGC certified genetic counselors have Master's degrees and extensive clinical training in counseling techniques.<sup>26</sup>

The FLAGC indicates that the bill's requirement to obtain ABGC board certification as a condition of licensure in Florida ensures potential licensees will have training in specialized fields of genetic medicine and clinical training in counseling techniques, equipping genetic counselors with the ability to respond to psychological demensions of medical issues and interpreting complex genetic testing results.<sup>27</sup> The FLAGC did not provide any data showing certified genetic counselors provide better or worse services than non-certified genetic counselors. ABGC is the only entity that certifies genetic counselors.

#### Unreasonable Effect on Job Creation or Job Retention

According to the FLAGC, licensure of genetic counselors will not affect other professionals whose scopes of services overlap with genetic counselors. Other health care practitioners, such as physicians and nurses, will still be able to provide genetic assessment, advice, and referral. Licensure requirements would mirror the current education requirements for board-certification by the ABGC. The

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<sup>&</sup>lt;sup>22</sup> The Florida Association of Genetic Counselors, Sunrise Review for Proposed Licensing of Genetic Counselors.

<sup>&</sup>lt;sup>23</sup> Id.

<sup>&</sup>lt;sup>24</sup> Emory Univeristy School of Medicine, *Genetic Counseling Profession – What is Genetic Counseling?*<a href="https://med.emory.edu/departments/human-genetics/education/genetic-counseling-training/profession/index.html">https://med.emory.edu/departments/human-genetics/education/genetic-counseling-training/profession/index.html</a> (last visited April 30, 2021).

<sup>&</sup>lt;sup>25</sup> Supra, note 6. See also supra, note 8.

<sup>&</sup>lt;sup>26</sup> Supra, note 8.

<sup>&</sup>lt;sup>27</sup> Supra, note 22.

FLAGC estimates 98% of practicing genetic counselors in Florida are board-certified or eligible for board certification; meaning the requirements for licensure imposed by the bill would negatively impact very few individuals currently providing genetic counseling services in this state.<sup>28</sup> However, this cannot be independently verified, as it is unknown how many genetic counselors not certified by ABGC practice in Florida.

The FLAGC also believes licensure will help attract and retain genetic counselors in this state by creating more training opportunities and increased competition in the field.<sup>29</sup>

### Effective Public Protection by Other Means

Current law does not require licensure or regulation of genetic counselors, meaning there is no regulatory authority for discipline of such individuals. 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 adhere to a scope of practice, mandate continuing education, regulate and impose discipline that will better protect the public, and allow credentialing in order to fully integrate into health care systems.<sup>30</sup>

Currently, the only recourse against a genetic counselor is action against his or her board certification. However, such action will not affect a genetic counselor who is not board certified, nor affect the ability of a genetic counselor to work as board certification is not a requirement for employment as a genetic counselor.

Because there is no data on bad outcomes or lack of public safety currently, it is impossible to measure any public safety improvement from a licensure program or from other means.

# Favorable Cost-effectiveness and Economic Impact

The FLAGC asserts that the economic benefit and cost savings realized through state licensure of genetic counselors would outweigh the administrative and fiscal impact to the state. Authorizing licensure of genetic counselors would help increase the number of genetic counselors employed within the state, according to the FLAGC, which will:<sup>31</sup>

- 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.

The FLGAC indicates patients will experience cost savings for genetic counseling services if genetic counselors are licensed. According to the FLAGC, the cost for genetic counseling services is less if such services are billed under the genetic counselor's name than if billed by a physician who provides the same services.<sup>32</sup>

The FLGAC asserts that genetic counselors are specially trained to identify the correct and most costeffective test for patients. One study shows genetic counselors save hospital systems an average of \$48,000 per month by reducing unnecessary testing when a genetic counselor reviews genetic testing orders.<sup>33</sup> Additional studies show an average cost savings of \$2000 per testing order review by a

<sup>29</sup> ld.

<sup>&</sup>lt;sup>28</sup> ld.

<sup>&</sup>lt;sup>30</sup> ld.

<sup>&</sup>lt;sup>31</sup> ld.

<sup>32</sup> L-I

<sup>&</sup>lt;sup>33</sup> Christine E. Miller, et al, Genetics Division, ARUP Laboratories, Salt Lake City, Utah, "Genetic counselor review of genetic testing orders in a reference laboratory reduces unnecessary testing," (March 2014), available at: <a href="https://pubmed.ncbi.nlm.nih.gov/24665052/">https://pubmed.ncbi.nlm.nih.gov/24665052/</a>.

genetic counselor<sup>34</sup> and \$3 million to \$5 million cost savings per year when genetic counselors review hereditary cancer testing orders.<sup>35</sup>

The FLAGC provided no studies or data demonstrating expanded patient access to services, reduced out-of-pocket costs, and positive economic benefit to the state by increasing workforce opportunities.

#### Effect of the Bill

The bill creates the "Genetic Counseling Workforce Act," adding genetic counselors to the list of health care practitioners requiring licensing and regulation by DOH.

# Scope of Practice

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.

<sup>&</sup>lt;sup>34</sup> Emily Wakefiled, et al, Division of Human Genetics, Cincinnati Children's Hospital Medical Center, "Reduction in Health Care Costs and Improved Appropriateness of Incoming Test Orders: the Impact of Genetic Counselor Review in an Academic Genetic Testing Laboratory," (February 2018), available at: <a href="https://pubmed.ncbi.nlm.nih.gov/29427196/">https://pubmed.ncbi.nlm.nih.gov/29427196/</a>.

<sup>&</sup>lt;sup>35</sup> Serenedy Smith, et al, Myriad Genetic Laboratories, Inc., Salt Lake City, Utah, "Optimization of quality assurance to increase clinical utility and cost effectiveness of hereditary cancer testing," (March 2017), available at: <a href="https://pubmed.ncbi.nlm.nih.gov/29767585/">https://pubmed.ncbi.nlm.nih.gov/29767585/</a>.

### Licensure

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.

### **Prohibtions and Penalties**

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.

#### Discipline

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:
  - o 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.

### **Exemption from Licensure**

The bill provides an exemption from licensure as a genetic counselor to 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.

#### Licensure Fees

The bill appropriates \$41,535 in recurring funds and \$4,429 in nonrecurring funds from the Medical Quality Assurance Trust Fund to the DOH to fund the costs of regulating genetic counselors. The MQA Trust Fund's sources of revenue are licensure fees and fines paid by the health care professions licensed under ch. 456, F.S.

Unlike all other professions and occupations regulated by DOH, the bill does not require an applicant to pay a fee for licensure or licensure renewal. Section 456.025, F.S., states that it is the intent of the legislature that all costs of regulating health care professions will be borne solely by licensees and licensure applicants. That section requires DOH, when setting licensure fees, to set fees that ensure that each profession is self-sustaining; that is, the cost of regulatory functions for one profession should not be subsidized by fees from another profession or by other sources, such as taxpayers.<sup>36</sup>

# Conscience Clause

The bill authorizes a genetic counselor to decline to participate in counseling that conflicts with the practitioner's moral or religious beliefs and prohibits DOH from making licensure contingent upon participation in such counseling. A genetic counselor who declines to provide couseling due to moral or religious beliefs may not be disciplined by DOH. Such refusal may also not be used as a basis for claim of damages if the genetic counselor informs the patient of the refusal to participate and and directs the patient to the DOH practitioner database.

The bill makes conforming technical and conforming changes.

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

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

# A. FISCAL IMPACT ON STATE GOVERNMENT:

<sup>36</sup> S. 456.025(1), F.S.

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		None. <sup>37</sup>	
	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. $^{38}$	
		DOH will incur costs associated with the regulation and licensure of genetic counselors. The bill appropriates \$41,535 in recurring funds and \$4,429 in nonrecurring funds from the Medical Quality Assurance Trust Fund to the DOH to fund one OPS position. DOH will use licensure fees paid by other professions to pay for any additional costs beyond these amounts.	
В.	FIS	FISCAL IMPACT ON LOCAL GOVERNMENTS:	
	1.	Revenues:	
		None.	
	2.	Expenditures:	
		None.	
C.	DIF	DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:	
		netic counselors will incur no costs associated with obtaining licensure by DOH, as these costs will covered by General Revenue and by other professions' licensure fees.	
D.	FIS	SCAL COMMENTS:	

None.

1. Revenues:

<sup>38</sup> Department of Health, Agency Analysis of 2021 House Bill 1233 (March 22, 2021).

<sup>&</sup>lt;sup>37</sup> Article VII, s. 19(a)-(b) of the Florida Constitution provides that no state tax or fee may be imposed, authorized, or raised by the Legislature except through legislation approved by two-thirds of the membership of each house of the Legislature. HB 1235, the fee bill linked to HB 1233, authorized DOH to charge an application fee of \$25 and an annual renewal fee not to exceed \$25 for a genetic counselor license. HB 1235 was not approved by the Legislature.