

March 9, 2021

The Honorable Justine Caldwell
Rhode Island House of Representatives

The Honorable Robert Craven
Rhode Island House of Representatives

The Honorable Katherine Kazarian
Rhode Island House of Representatives

Re: Rhode Island House Bill 5147

Dear Representatives Caldwell, Craven, Kazarian, McEntee, Ruggiero:

On behalf of the American College of Medical Genetics and Genomics (ACMG¹), we are reaching out to you about House Bill 5147 which would establish licensure requirements for genetic counselors in the state of Rhode Island. ACMG strongly supports establishment of state licensure requirements for genetic counselors. However, we cannot support state licensure that would allow genetic counselors to engage in the independent practice of medicine. Moreover, we are aware that you already have received at least one suggested amendment that specifically would expand the scope of practice for genetic counselors. Accordingly, we have provided below some clarifying information and suggested amendments that we hope will be of assistance as you consider these issues.

Genetic counselors work as part of the medical team to facilitate communication between patients and other healthcare providers on health issues with a genetic component. They receive specialized training in counseling patients to help them understand the medical, psychological, and familial implications of genetic information and findings. After two years, this training leads to a master's degree in genetic counseling, and individuals are eligible for certification by the American Board of Genetic Counseling. However, genetic counselors are not trained to practice medicine.

The practice of medicine requires doctoral-level medical training followed by several years of additional specialized training. The following activities constitute the practice of medicine:

The Honorable Carol McEntee
Rhode Island House of Representatives

The Honorable Deborah Ruggiero
Rhode Island House of Representatives

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- 1) ordering medical tests, including genetic testing;
- 2) establishing a clinical diagnosis for a patient;
- 3) performing a medical examination of a patient;
- 4) medical management of a patient; and
- 5) medical treatment of a patient.

To ensure that patients in Rhode Island are receiving proper clinical care, we recommend the following amendments for H 5147:

Nothing in this title authorizes a genetic counselor to practice medicine, including diagnosis, treatment, or medical management of a patient.

If, in the course of providing genetic counseling to a client, a genetic counselor finds any indication of a disease or condition that requires medical assessment, diagnosis, or treatment, the genetic counselor shall refer the client to a physician licensed to practice medicine.

We also want to provide a technical clarification. The organization that certifies medical geneticists is the American Board of Medical Genetics and Genomics, abbreviated as ABMGG. The definition in section 5-90-3(2) should be updated to reflect the proper name, and references to ABMGG throughout the bill should also be updated.

In addition, we are aware that you have received a proposed amendment that would expand the scope of practice for genetic counselors to include the independent ordering of genetic tests and any other diagnostic studies, among other changes. Ordering of tests by a genetic counselor means that the results are returned to the counselor who is then interpreting those results and returning them to the patient without a physician being involved.

As noted above, the ordering of medical tests is part of the practice of medicine. While there are certain types of genetic tests that may safely be ordered by an appropriately trained genetic counselor, such as those that are used to estimate the risk of developing disease or to guide family planning decisions, other genetic tests confer a diagnosis or guide treatment decisions. Genetic counselors are not trained to diagnose or treat patients. The ordering of such tests should be performed only by a physician or by a genetic counselor working collaboratively with the patient's licensed physician. We recognize that some medical specialists may feel comfortable with having a genetic counselor independently order genetic tests that are routine to their practice. However, this does not hold true for many specialties that incorporate genetic testing to diagnose or inform medical management of their

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patients. For example, for patients with complex chronic undiagnosed conditions, a physician trained in genetics should be involved in deciding what test to order and interpreting the results.

Most genetic counselors do work closely with physicians as part of a medical team. They provide important services that the physicians and patients rely on. However, independent genetic counseling practices and private companies also exist. The potential for non-physician providers to independently order genetic or other medical tests that inform a diagnosis or guide treatment decisions without any prior or concurrent engagement between the patient and physician places the public at risk. For such tests to be ordered responsibly, patients must be seen by a healthcare provider educated and trained to diagnose and treat patients.

Accordingly, if you are considering inclusion of a scope of practice that would allow genetic counselors to order medical tests, we strongly recommend inclusion of a requirement for a collaborative agreement with a physician. The agreement must be formally documented and should describe the relationship between the genetic counselor and the physician, such as whether there is a need for a co-signature when ordering genetic tests, and criteria governing the genetic counselor's performance of medical activities. These agreements could be tailored to be appropriate for different types of practices relying on genetic testing.

With the rapid increase in knowledge about the relationships between genetics and disease that has developed over the past several decades, genetic services have become increasingly more complex and require a unique combination of medical knowledge and counseling skills. As such, it is particularly important for genetic counselors and physicians to work collaboratively in team environments to ensure that patients are receiving the best care possible.

ACMG supports the establishment of state licensure programs for genetic counselors and believes that licensure enhances the ability of genetic counselors to provide appropriate genetic counseling services to those who need them. Furthermore, licensure helps protect the public from the harms that would ensue from inaccurate and inappropriate counseling that could be provided by inadequately trained individuals holding themselves out to the public as genetic counselors. However, we strongly believe that genetic counselors should be licensed only to provide genetic counseling services and not to practice medicine.

ACMG appreciates your attention to this important issue and is hopeful that you will take this information into consideration for House Bill 5147. ACMG is available to further discuss these concerns or to provide technical assistance in

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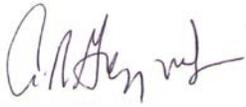
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refining legislative language if needed, including providing language from other states that have successfully implemented genetic counseling licensure while also permitting ordering of medical tests under collaborative agreements with physicians.

Sincerely,



Anthony R. Gregg, MD, MBA, FACOG, FACMG
President
American College of Medical Genetics and Genomics



Maximilian Muenke, MD, FACMG
Chief Executive Officer
American College of Medical Genetics and Genomics

ⁱ ACMG is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. ACMG is the largest membership organization specifically for medical geneticists, providing education, resources, and a voice for more than 2,400 clinical and laboratory geneticists, genetic counselors, and other healthcare professionals, nearly 80% of whom are board-certified in the medical genetics specialties. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

The specialty of medical genetics includes clinical geneticists (MD/DO or equivalent), PhD medical geneticists (PhD), and laboratory geneticists (MD/DO or PhD or equivalent), as well as the clinical subspecialty of medical biochemical genetics (MD/DO or equivalent). These medical geneticists are board-certified by the American Board of Medical Genetics and Genomics (ABMG), one of the 24 member boards of the American Board of Medical Specialties.

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