

March 9, 2021

The Honorable Linda Rosenthal  
New York State Assembly

The Honorable Michael Benedetto  
New York State Assembly

The Honorable Richard Gottfried  
New York State Assembly

The Honorable David McDonough  
New York State Assembly

The Honorable Nily Rozic  
New York State Assembly

The Honorable Albert Stirpe  
New York State Assembly

**Re: New York Assembly Bill 2151**

Dear Assembly Members Rosenthal, Benedetto, Gottfried, McDonough, Rozic, and Stirpe:

The American College of Medical Genetics and Genomics (ACMG<sup>1</sup>) strongly supports establishment genetic counselor licensure requirements in the state of New York, and we encourage passage of appropriate legislation. However, amendments are needed before we can support A 2151 because, as currently written, A 2151 would allow genetic counselors to independently engage in the practice of medicine. We have provided below some clarifying information and recommended 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:

- 1) ordering medical tests, including genetic testing;
- 2) establishing a clinical diagnosis for a patient;

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- 3) performing a medical examination of a patient;
- 4) medical management of a patient; and
- 5) medical treatment of a patient.

Assembly Bill 2151 is intended to establish licensure for genetic counselors which includes establishing a defined scope of practice. However, as currently worded, Section 7051(1) would expand the scope of practice for genetic counselors to engage in the practice of medicine. Section 7051(1) starts by explaining that the practice of genetic counseling means the *communication to and education of human clients, their families, other health care professionals and the general public with regard to genetic testing, individual family histories, or other genetic, personal medical history, and technical information associated with the occurrence, risk of occurrence or recurrence, of a genetic or hereditary condition or birth defect*. However, the language then proceeds to specify activities that go beyond communication and education and cross into the practice of medicine.

Specifically, A 2151 would allow genetic counselors to independently order medical tests, including genetic tests. 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 can 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. As appropriately stated in Section 7051(2), genetic counselors should not be authorized to diagnose or treat patients. The ordering of such tests, as well as interpreting and returning results, should be performed only by physician or by a genetic counselor when they are working collaboratively with the patient's licensed physician.

As such, Section 7051(1) needs to be significantly modified either to exclude any activities that could constitute the practice of medicine or to require a collaborative agreement with a physician. Such agreements should be formally documented and should describe the relationship between the genetic counselor and the physician, including whether there is a need for a co-signature when ordering genetic tests.

These collaborative agreements could be tailored to be appropriate for different types of practices providing genetic testing. For example, Section 7051(1) of A 2151 could be modified to read as follows:

*(c) pursuant to a formally documented agreement with a physician that describes the collaborative relationship between the genetic counselor and the*

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*physician, and establishes criteria governing the genetic counselor's performance of medical activities, such as a co-signature requirement for ordering genetic tests that may provide diagnostic information or guide medical treatment:*

- (i) identify and order genetic laboratory tests and coordinate other diagnostic studies as appropriate for the genetic assessment;*
- (ii) integrate genetic laboratory test results and results from other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic conditions; and*
- (iii) explain to a patient the clinical implications of genetic laboratory tests and other diagnostic studies and their results.*

To further ensure patient safety, Section 7051(3) should be modified as underlined below:

*If in the course of providing genetic counseling to any client, a genetic counselor finds any indication of disease or condition that may require medical assessment, diagnosis, or treatment, the genetic counselor shall refer that client to a licensed physician, or as appropriate, another health care professional licensed pursuant to this title.*

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 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.

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

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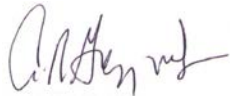
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knowledge and counseling skills. As such, it is particularly important for genetic counselors and physicians to work collaboratively in team environments to ensure that patients are receiving the best care possible.

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 Assembly Bill 2151. ACMG is available to further discuss these concerns or to provide technical assistance in 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  
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<sup>i</sup> 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

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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 (ABMGG), one of the 24 member boards of the American Board of Medical Specialties.

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