

January 25, 2021

The Honorable Clarence Lam
Maryland Senate
420 Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

Re: Maryland Senate Bill 34

Dear Senator Lam:

The American College of Medical Genetics and Genomics (ACMG) supports establishing state licensure programs for genetic counselors, however we want to draw your attention to significant concerns that must be addressed for any related legislation. 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 (ABMGG), one of the 24 member boards of the American Board of Medical Specialties.

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

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genetic counseling, and individuals are certified by the American Board of Genetic Counseling. However, genetic counselors are not trained to practice medicine, and we are extremely concerned that SB 34, as currently written, would expand genetic counselors' scope of practice to include the independent practice of 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;
- 3) performing a medical examination of a patient;
- 4) medical management of a patient; and
- 5) medical treatment of a patient.

Maryland Senate Bill 34 is intended to establish licensure for genetic counselors, which includes establishing a defined scope of practice. However, as currently worded, Section 14-5G-01(K) would expand the scope of practice for genetic counselors to include certain aspects of the practice of medicine. Specifically, SB 34 would allow genetic counselors to independently order genetic tests and other diagnostic studies. 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*.

While there are certain types of genetic tests that can safely be ordered by an appropriately trained genetic counselor, such as those that are only used to estimate risk of developing disease or guide family planning decisions, other genetic tests confer a diagnosis or guide treatment decisions. Genetic counselors are not trained to diagnose and treat patients. The ordering of such tests, as well as interpreting and returning results, should be performed only by a physician or by a genetic counselor working collaboratively with the patient's physician. Further, the language "other diagnostic studies" seems to imply that genetic counselors could even order diagnostics that are not of a genetic nature (e.g., CAT scans). It seems that an attempt to mitigate this concern was made by adding a definition for "genetic assessment". However, the inclusion of vague language may create the potential for interpretation that allows genetic counselors to independently engage in the practice of medicine.

As such, Section 14-5G-01(K) 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 must be formally documented and should describe the relationship between the genetic counselor and

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the physician, the need for a co-signature when ordering genetic tests, and criteria governing the genetic counselor's performance of medical activities. For example, Section 14-5G-01(K) of SB 34 could be modified to read as follows:

(III) pursuant to a formally documented agreement with a physician that describes the collaborative relationship between the genetic counselor and the physician, and establishes criteria governing the genetic counselor's performance of medical activities, including a co-signature requirement for ordering genetic tests that may provide diagnostic information or guide medical treatment:

(a) Identifying, ordering, and coordinating genetic laboratory tests and other diagnostic studies, as appropriate, for purposes of a genetic assessment; and

(b) Explaining the clinical implications of genetic laboratory tests and other diagnostic studies and the results of the tests and studies.

In addition, we recommend that Section 14-5G-12(B) be modified as underlined below.

If, while practicing genetic counseling, a licensed genetic counselor determines that a patient requires a medical assessment, diagnosis or treatment, the genetic counselor shall refer the patient to a licensed physician or another appropriate health care practitioner.

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 counseling skills and medical knowledge. 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 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 Senate Bill 34. ACMG is available

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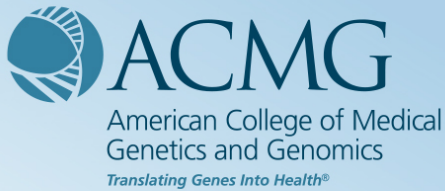
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to further discuss these concerns or to provide technical assistance in refining legislative language if needed.

Sincerely,

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

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