

March 12, 2020

The Honorable David Steffen Wisconsin State Assembly

The Honorable Jonathan Brostoff Wisconsin State Assembly

The Honorable Jimmy Anderson Wisconsin State Assembly

The Honorable Mark Born Wisconsin State Assembly

The Honorable Cindi Duchow Wisconsin State Assembly

The Honorable Joel Kitchens Wisconsin State Assembly

The Honorable Scott Krug Wisconsin State Assembly The Honorable Mike Kuglitsch Wisconsin State Assembly

Wisconsin State Assembly

The Honorable Barbara Dittrich Wisconsin State Assembly

The Honorable Steve Doyle Wisconsin State Assembly

The Honorable Todd Novak Wisconsin State Assembly

The Honorable Jesse L. James Wisconsin State Assembly

The Honorable John Spiros

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Rep.Dittrich@legis.wisconsin.gov; Rep.Doyle@legis.wisconsin.gov; Rep.Novak@legis.wisconsin.gov; Rep.James@legis.wisconsin.gov

Re: Wisconsin Assembly Bill 686

Dear Representatives Steffen, Brostoff, Anderson, Born, Duchow, Kitchens, Krug, Kuglitsch, Spiros, Dittrich, Doyle, Novak, and James:

On behalf of the American College of Medical Genetics and Genomics (ACMG), I want to draw your attention to significant concerns about Assembly Bill 686.

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ACMG is the only nationally recognized professional membership organization dedicated to improving health through the practice of medical genetics and genomics. Our membership includes over 2,300 genetics professionals, nearly 80% of which are board-certified clinical and laboratory geneticists and genetic counselors.

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 to manage 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 certified by the American Board of Genetic Counseling. However, genetic counselors are not trained to practice medicine, and we are extremely concerned that AB 686, as currently written, would expand genetic counselors' scope of practice to include the 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.

Wisconsin Assembly Bill 686 is intended to establish licensure for genetic counselors which includes establishing a defined scope of practice. However, as currently worded, Section 448.970(3) expands the scope of practice for genetic counselors to include certain aspects of practice of medicine. Specifically, AB 686 would allow genetic counselors to independently order any 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.

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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, and therefore ordering of such tests, as well as interpreting and returning results, should only be performed by a genetic counselor when they are working collaboratively with the patient's licensed 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).

As such, Section 448.970(3) needs to either be significantly modified to exclude any activities that could be interpreted as practice of medicine, or it should be modified to require a collaborative agreement with a physician. Such agreements must be formally documented and should describe the relationship between the genetic counselor and the physician, the need for a cosignature when ordering genetic tests, and criteria governing the genetic counselor's performance of medical activities. For example, Section 448.970(3) of AB 686 could be modified to read as follows:

- (c) pursuant to a formally documented collaborative 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 cosignature requirement for ordering genetic tests that may provide diagnostic information or guide medical treatment:
 - (i) Identify, coordinate, and order genetic laboratory tests and other diagnostic studies as appropriate for a genetic assessment.
 - (ii) Integrate 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.
 - (iii) Explain the clinical implications of genetic laboratory tests and other diagnostic studies and their results.

To further ensure patient safety, the following language should also be added to AB 686:

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

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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 or treatment, the genetic counselor shall refer the client to a physician licensed to practice medicine.

With the rapid increase in knowledge about the relationships between genetics and disease that has developed over the past couple 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 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 Assembly Bill 686. ACMG is available to further discuss these concerns or to provide technical assistance in refining legislative language if needed.

Sincerely,

Anthony R. Gregg, MD, MBA, FACOG, FACMG

President

American College of Medical Genetics and Genomics

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

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