

February 24, 2020

The Honorable Vaneta Becker  
Indiana State Senate

The Honorable Ann Vermilion  
Indiana House of Representatives

Sent electronically to: Senator.Becker@iga.in.gov, Micha.Sabec@iga.in.gov,  
h31@iga.in.gov

**Re: Indiana House Bill 1243**

Dear Senator Becker and Representative Vermilion:

On behalf of the American College of Medical Genetics and Genomics (ACMG), I want to draw your attention to significant concerns about HB 1243. 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 HB 1243, as currently written, would expand genetic counselors' scope of practice to include the practice of medicine.

**Officers**

Anthony R. Gregg, MD, MBA, FACMG  
President

Louanne Hudgins, MD, FACMG  
Past-President

Marc Williams, MD, FACMG  
President-Elect

Susan D. Klugman, MD, FACMG  
Vice-President of Clinical Genetics

Elaine Lyon, PhD, FACMG  
Vice-President of Laboratory Genetics

Catherine W. Rehder, PhD, FACMG  
Treasurer

Amy E. Roberts, MD, FACMG  
Secretary

**Directors**

Tina M. Cowan, PhD, FACMG  
Biochemical Genetics

Laurie A. Demmer, MD, FACMG  
Clinical Genetics

Karen Gripp, MD, FACMG  
Clinical Genetics

Dietrich Matern, MD, PhD, FACMG  
Biochemical Genetics

Michael Murray, MD, FACMG  
Clinical Genetics

Katy C. Phelan, PhD, FACMG  
Cytogenetics

Cynthia Powell, MD, FACMG  
Clinical Genetics

Heidi Rehm, PhD, FACMG  
Molecular Genetics

**Ex Officio**

Robert D. Steiner, MD, FACMG  
Editor-in-Chief, *Genetics in Medicine*

Bruce R. Korf, MD, PhD, FACMG  
ACMG Foundation Liaison

**Legal Counsel**

Lynn D. Fleisher, PhD, JD, FACMG  
Legal Counsel

**Executive Office**

Maximilian Muenke, MD, FACMG  
Chief Executive Officer

7101 Wisconsin Avenue  
Suite 1101, Bethesda, MD 20814  
Telephone: 301-718-9603  
Fax: 301-718-9604

[www.acmg.net](http://www.acmg.net)

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.

Indiana House Bill 1243 is intended to significantly modify the existing genetic counselor licensure law in Indiana by expanding the scope of practice for genetic counselors to include certain aspects of practice of medicine. Specifically, HB 1243 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.

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 genetic.

As such, items 3-5 of Section 1 need to either be modified to exclude any activities that could be interpreted as practice of medicine, or they should be modified to require a collaborative agreement with a physician. Such agreements must be formally documented and should describe the supervisory relationship between the genetic counselor and the physician, including a cosignature requirement for ordering genetic tests and establish criteria governing the genetic counselor's performance of medical activities. For example, Section 1 of HB 1243 could be modified to read as follows:

*(3) 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*

## Officers

Anthony R. Gregg, MD, MBA, FACMG  
President

Louanne Hudgins, MD, FACMG  
Past-President

Marc Williams, MD, FACMG  
President-Elect

Susan D. Klugman, MD, FACMG  
Vice-President of Clinical Genetics

Elaine Lyon, PhD, FACMG  
Vice-President of Laboratory Genetics

Catherine W. Rehder, PhD, FACMG  
Treasurer

Amy E. Roberts, MD, FACMG  
Secretary

## Directors

Tina M. Cowan, PhD, FACMG  
Biochemical Genetics

Laurie A. Demmer, MD, FACMG  
Clinical Genetics

Karen Gripp, MD, FACMG  
Clinical Genetics

Dietrich Matern, MD, PhD, FACMG  
Biochemical Genetics

Michael Murray, MD, FACMG  
Clinical Genetics

Katy C. Phelan, PhD, FACMG  
Cytogenetics

Cynthia Powell, MD, FACMG  
Clinical Genetics

Heidi Rehm, PhD, FACMG  
Molecular Genetics

## Ex Officio

Robert D. Steiner, MD, FACMG  
Editor-in-Chief, *Genetics in Medicine*

Bruce R. Korf, MD, PhD, FACMG  
ACMGF Foundation Liaison

## Legal Counsel

Lynn D. Fleisher, PhD, JD, FACMG  
Legal Counsel

## Executive Office

Maximilian Muenke, MD, FACMG  
Chief Executive Officer

7101 Wisconsin Avenue  
Suite 1101, Bethesda, MD 20814  
Telephone: 301-718-9603  
Fax: 301-718-9604

[www.acmg.net](http://www.acmg.net)

*requirement for ordering genetic tests that may provide diagnostic information or guide medical treatment:*

- (a) Identify, order, and coordinate genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment.*
- (b) Integrate genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate genetic risk factors.*
- (c) Explain the clinical implications of genetic laboratory tests, other diagnostic studies, and the results.*

To further ensure patient safety, the following language should also be added to HB 1243:

*Nothing in this chapter 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 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.

Additionally, ACMG cannot support certain provisions unrelated to licensure, including those related to social issues such as so-called “conscience clauses” that would allow genetic counselors to refuse to counsel on medical options based on moral or religious beliefs. As with all healthcare providers, genetic counselors should always provide the full breadth of information to patients so they can make informed decisions that are best for them and their family.

ACMG appreciates your attention to this important issue and is hopeful that the Health and Provider Services Committee will take this information into consideration as you consider House Bill 1243. ACMG is available to further discuss these concerns or to provide technical assistance in refining legislative language if needed.

#### Officers

Anthony R. Gregg, MD, MBA, FACMG  
President

Louanne Hudgins, MD, FACMG  
Past-President

Marc Williams, MD, FACMG  
President-Elect

Susan D. Klugman, MD, FACMG  
Vice-President of Clinical Genetics

Elaine Lyon, PhD, FACMG  
Vice-President of Laboratory Genetics

Catherine W. Rehder, PhD, FACMG  
Treasurer

Amy E. Roberts, MD, FACMG  
Secretary

#### Directors

Tina M. Cowan, PhD, FACMG  
Biochemical Genetics

Laurie A. Demmer, MD, FACMG  
Clinical Genetics

Karen Gripp, MD, FACMG  
Clinical Genetics

Dietrich Matern, MD, PhD, FACMG  
Biochemical Genetics

Michael Murray, MD, FACMG  
Clinical Genetics

Katy C. Phelan, PhD, FACMG  
Cytogenetics

Cynthia Powell, MD, FACMG  
Clinical Genetics

Heidi Rehm, PhD, FACMG  
Molecular Genetics

#### Ex Officio

Robert D. Steiner, MD, FACMG  
Editor-in-Chief, *Genetics in Medicine*

Bruce R. Korf, MD, PhD, FACMG  
ACMGF Foundation Liaison

#### Legal Counsel

Lynn D. Fleisher, PhD, JD, FACMG  
Legal Counsel

#### Executive Office

Maximilian Muenke, MD, FACMG  
Chief Executive Officer

7101 Wisconsin Avenue  
Suite 1101, Bethesda, MD 20814  
Telephone: 301-718-9603  
Fax: 301-718-9604

[www.acmg.net](http://www.acmg.net)



American College of Medical  
Genetics and Genomics  
*Translating Genes Into Health®*

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

#### Officers

Anthony R. Gregg, MD, MBA, FACMG  
President

Louanne Hudgins, MD, FACMG  
Past-President

Marc Williams, MD, FACMG  
President-Elect

Susan D. Klugman, MD, FACMG  
Vice-President of Clinical Genetics

Elaine Lyon, PhD, FACMG  
Vice-President of Laboratory Genetics

Catherine W. Rehder, PhD, FACMG  
Treasurer

Amy E. Roberts, MD, FACMG  
Secretary

#### Directors

Tina M. Cowan, PhD, FACMG  
Biochemical Genetics

Laurie A. Demmer, MD, FACMG  
Clinical Genetics

Karen Gripp, MD, FACMG  
Clinical Genetics

Dietrich Matern, MD, PhD, FACMG  
Biochemical Genetics

Michael Murray, MD, FACMG  
Clinical Genetics

Katy C. Phelan, PhD, FACMG  
Cytogenetics

Cynthia Powell, MD, FACMG  
Clinical Genetics

Heidi Rehm, PhD, FACMG  
Molecular Genetics

#### Ex Officio

Robert D. Steiner, MD, FACMG  
Editor-in-Chief, *Genetics in Medicine*

Bruce R. Korf, MD, PhD, FACMG  
ACMGF Foundation Liaison

#### Legal Counsel

Lynn D. Fleisher, PhD, JD, FACMG  
Legal Counsel

#### Executive Office

Maximilian Muenke, MD, FACMG  
Chief Executive Officer

7101 Wisconsin Avenue  
Suite 1101, Bethesda, MD 20814  
Telephone: 301-718-9603  
Fax: 301-718-9604

[www.acmg.net](http://www.acmg.net)