

February 25, 2021

The Honorable Brian Higgins
U.S. House of Representatives
2459 Rayburn House Office Building
Washington, DC 20515

Re: Access to Genetic Counselor Services Act

Dear Representative Higgins:

The American College of Medical Genetics and Genomics (ACMG) appreciates your interest in establishing Medicare reimbursement for services provided by board-certified genetic counselors. ACMG is very supportive of ensuring that genetic counselors are appropriately reimbursed for providing genetic counseling services. However, we cannot support the reimbursement of genetic counselors for the practice of medicine. Accordingly, as you prepare a new bill on reimbursement for genetic counseling services, which was the primary focus of the former Access to Genetic Counselor Services Act of 2019, we want to provide clarifying information for your consideration.

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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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 educated or trained to diagnose or treat patients. The diagnosis and treatment of patients falls within the scope of 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.

The established scope of practice for genetic counselors varies among states. Currently 29 states have licensure requirements for genetic counselors which is traditionally where scope of practice is defined. Of the states requiring licensure, some explicitly allow genetic counselors to order genetic and/or other medical tests independently, some require collaboration with a physician, some specifically prohibit ordering of tests, and others include vague language (e.g., identify and coordinate) that does not specifically address ordering of medical tests and is interpreted differently among states.

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 and treat patients. However, in certain cases, genetic tests should be ordered only after a patient has received a diagnosis from a physician. Others may require physician involvement to complete a diagnostic interpretation of results. While we believe that the majority of genetic counselors will continue to responsibly order only certain types of tests, and only when appropriate criteria are met, precautions need to be added to legislation to ensure that Medicare is only covering medical tests that are appropriately ordered.

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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 is extremely problematic. For such tests to be ordered responsibly, patients must be seen by a healthcare provider educated and trained to diagnose and treat patients.

While it is not uncommon for a non-physician provider to assist physicians with certain aspects of the practice of medicine, such activities generally require supervision by or collaboration with a physician. Currently the Social Security Act (SSA) requires that many non-physician providers work with physicians in order to be reimbursed for services that otherwise would be furnished by a physician. For example, the SSA recognizes such services performed by a physician assistant when *performed under the supervision of a physician and which the physician assistant is legally authorized to perform by the state in which the services are performed*. Similarly, for nurse practitioners and clinical nurse specialists, the SSA recognizes such services provided *when working in collaboration with a physician which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the state in which the services are performed*.

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.

To address these concerns, we previously recommended the following language for the Access to Genetic Counselor Services Act of 2019:

The term ‘covered genetic counseling services’ means genetic counseling services furnished by a genetic counselor (as defined in paragraph (2)) pursuant to a formally-documented collaborative agreement with a physician (as defined in subsection (r)(1)) (and such services and supplies furnished as an incident to the provision of such services) as would otherwise be covered under this title if furnished by a physician (or as incident to a physician’s service), but does not include the diagnosis or treatment of patients.

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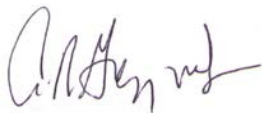
The intent of our recommended language is to allow for flexible collaborative agreements, not supervision, that can be tailored by individual practices to accommodate their specialty, the types of patients they treat, and the types of genetic and other medical tests on which they rely. We would be happy to work with your office in developing language for a new version of this legislation.

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 to work collaboratively with physicians in team environments to ensure that patients are receiving the best care possible. Moreover, collaboration between genetic counselors and physicians is likely to reduce instances of ordering of unnecessary or incorrect genetic tests.

ACMG supports the direct reimbursement of genetic counselors by Medicare – for the provision of genetic counseling services. Better reimbursement allows medical institutions to hire more genetic counselors. However, if Medicare is going to cover services provided by genetic counselors that fall under the practice of medicine, then collaboration with a physician licensed to practice medicine is essential.

ACMG appreciates your careful consideration of these comments and looks forward to working with you to ensure that patient safety remains a priority. For additional questions or comments, please contact Dr. Michelle McClure, ACMG's Public Policy Director, at mmclure@acmg.net.

Sincerely,



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