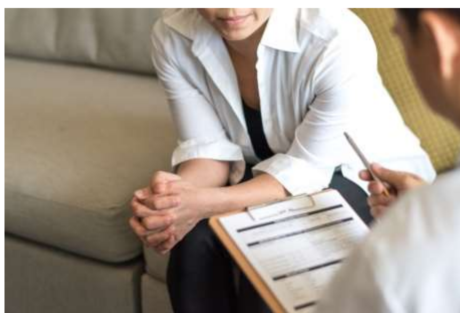
Genetic Counselors Medicare Payment Bill Gaining Support Despite 'Scope of Practice' Disagreement

Feb 11, 2020 | Turna Ray



NEW YORK – A bill to amend federal law and allow genetic counselors to bill Medicare for the services they provide is gaining support in Congress and in the broader healthcare community.

However, despite widespread support and bipartisan sponsorship, one professional organization representing medical geneticists and genetic counselors says it won't support the bill unless it explicitly states that genetic counselors cannot receive Medicare reimbursement for ordering tests.

The broader genetic counseling community feels slighted by the American College of Medical Genetics and Genomics' stance and believes it reflects the view of some of their medical genetics colleagues. The disagreement has also provided genetic counselors an opportunity to educate lawmakers and the public about the increasing importance of counselors in the precision medicine era, particularly when it comes to ordering the right tests, which in turn helps avoid inappropriate care and wasteful spending.

Broadly speaking, genetic counselors help patients understand the genetic underpinnings of diseases they may already have, or in otherwise healthy individuals, explain how a genetic finding might increase their risk for a disease. In some states, counselors can order genetic tests and explain or interpret what the results mean in the context of patients' health and family history. However, the Centers for Medicare & Medicaid Services doesn't recognize genetic counselors as healthcare providers. This means that doctors, even those with little or no genetics training, can bill Medicare for genetic counseling and related services, but master's degree-trained genetic counselors cannot.

H.R. 3235, "Access to Genetic Counselors Services Act of 2019," would change the Social Security Act so that genetic counselors who are licensed in their state (or who meet other specified criteria in states that don't have licensure) could receive Medicare payment for the work they do. The bill doesn't enumerate the specific covered activities, but it also doesn't restrict doctors from getting paid for the same work. The bill further stipulates that when genetic counselors provide counseling and other incidental services, they would be reimbursed at 85 percent of the fee that physicians would get for performing the same services.

For well over a decade, the National Society of Genetic Counselors has wanted to resolve the Medicare billing issue for its members, but past efforts to advance legislation have gained little traction. In 2018, NSGC was successful in getting a bill (H.R. 7083) introduced in the House.

H.R. 3235, which has essentially the same language as the earlier bill, was reintroduced again last June, in the 116th Congress, with Dave Loebsack (D-Iowa) as the sponsor. The bill so far has garnered 17 cosponsors — 10 Democrats and seven Republicans — and has been referred to the House Energy and Commerce Committee and the House Ways and Means Committee.

The bipartisan bill, in a highly partisan Congress, speaks to the work NSGC has put behind raising awareness of the issues at play. NSGC leadership met with members of Congress last week to encourage them to make this bill a priority and place it on the legislative schedule. The broader genetic counseling community has also become organized around raising awareness of the bill. Many genetic counselors in recent weeks have changed their social media profile pictures to a "I support H.R. 3235" graphic.

Los Angeles-based genetic counselor Dena Goldberg designed that graphic and created a webpage to educate the public about the bill after several genetic counseling colleagues reached out to her about developing an online campaign in light of ACMG's stance. "There's power when a large crowd is using unified tools," said Goldberg. "The key is spreading awareness … so this becomes a popular topic not just among the genetic counseling community but in the wider community. That's when we may be able to see some change."

So far, more than 250 organizations have signed on to NSGC's letter of support for H.R. 3235, including genetic testing companies such as ARUP laboratories, Ambry Genetics, Invitae, and Myriad Genetics; large reference labs such as Quest Diagnostics and Laboratory Corporation of America; and well known cancer centers and healthcare systems with personalized medicine programs including Memorial Sloan Kettering, Geisinger, Intermountain Healthcare – Precision Genomics, Brigham and Women's Hospital, and Moffitt Cancer Center. Numerous patient advocacy organizations are behind H.R. 3235, and several professional organizations including the American Society of Human Genetics, the Association of Community Cancer Centers, and the Personalized Medicine Coalition are also backing it.

Politics of payment

Still, "enacting any legislation is inherently a political process," acknowledged John Richardson, NSGC's director of government relations and advocacy. And there are organizations, like the ACMG, that don't support the bill as written, though he said he is not aware of any other groups that have explicitly made their opposition known to legislators.

The ACMG, however, wrote to legislators in January that while the group values the services provided by genetic counselors and supports their ability to receive Medicare payment for counseling patients, the organization cannot back any policies that would allow master's degree-trained genetic counselors to practice medicine. The practice of medicine, as defined by the ACMG, includes ordering medical tests, establishing a clinical diagnosis, performing a medical examination, determining the medical management of a patient, and prescribing treatment for a patient.

The ACMG's position is disappointing, said NSGC President Gillian Hooker, but it's one that they've maintained for some time. She noted that the NGSC has never asserted that genetic counselors should be able to diagnose, medically examine and manage patients, or prescribe treatment. "Those are clearly within the scope of a physician's practice, and not what we're training genetic counselors for," she said.

Where the NSGC and ACMG disagree is on the ability of counselors to order genetic tests. "The ordering of genetic tests is much more specific and narrow, and there's a good body of evidence to support the competency of genetic counselors in that area," she added.

For example, a 2013 study showed that 26 percent of germline test orders by healthcare providers were changed after genetic counselors at ARUP Laboratories reviewed them to ensure the most clinically useful tests based on patients' medical and family history were being ordered. Having genetic counselors double

check healthcare providers' test orders resulted in an average of $48,000 in savings for referring institutions. Moreover, there is mounting research attesting to the fact that most doctors lack genetics expertise and are uncertain how to incorporate genetic testing into practice.

NSGC and ACMG have made multiple attempts to come to a compromise on the bill language, but this matter of genetic counselors' ability to order genetic tests continues to be the main sticking point. NSGC would like state licensure laws to continue to define counselors' "scope of practice," or what they can and can't do professionally.

CMS decides what services it will pay for under Medicare and when those services need to be performed by a healthcare provider. However, it is up to the states, not CMS, to define the scope of practice for a healthcare provider, and it is the NSGC's position that the same should apply to genetic counselors.

In the majority of states, licensure laws allow counselors to "identify and coordinate" genetic testing; Pennsylvania explicitly forbids test ordering by genetic counselors. In around 10 states, licensure laws do allow test ordering. If H.R. 3235 passes as written, it would allow genetic counselors to get paid for the counseling services they provide, and whether they'd be allowed to order and interpret tests would be stipulated by the state's licensure laws, but either way it wouldn't change the Medicare payment rate.

The ACMG, however, does not support the trend in state laws to allow greater autonomy to genetic counselors when it comes to ordering and interpreting tests. "In the few states where this authority has been granted, H.R. 3235, as currently written, would allow counselors to be reimbursed for those activities, thus creating a pathway for counselors to independently practice medicine," said ACMG President Anthony Gregg.

The organization would also like to see the bill include language that requires a physician to be involved in interpreting test results. "The interpretation part is where we can't budge very much on," said Gregg. "If you get a positive result, physicians have to be involved in communicating to the patient what that means."

In a letter to its members, Gregg and ACMG CEO Maximilian Muenke noted that the genetics society's position is in line with the American Medical Association, which considers the interpretation of medical tests to be the practice of medicine and maintains that it should be done under the supervision of a licensed physician. Additionally, the College of American Pathologists worked with the New Jersey Society of Pathologists to amend the genetic counseling licensure law in the state and remove the authorization of genetic counselors to interpret genetic tests during the 2012-2013 legislative session.

When asked whether there is any evidence showing that counselors need to work under physician authority because on their own they order the wrong tests, ACMG said it wasn't aware of such data, but added, "We have to remember that counselors have, to date, mostly practiced with physician oversight."

The idea that genetic counselors cannot provide counseling unless under the supervision of a medical geneticist or a physician, when most doctors have limited genetics training, lacks credibility, NSGC's Richardson argued. "We are trying to expand patient access to genetic services. In all of our state licensure laws, whether it allows genetic counselors to order tests or not, the regulation allows independent practice," he said. "Nowhere are genetic counselors required to be under the supervision of a physician."

Moreover, most states don't explicitly forbid test ordering by genetic counselors. In California, for example, the state law says genetic counselors can "identify" and "coordinate" genetic testing, but doesn't specifically include the word "order." As a result, Amie Blanco, director of UCSF's Cancer Genetics and Prevention Program, said that her institution has decided that physicians will have to order testing.

Regardless, she objected to the idea that just because genetic counselors aren't doctors that they automatically should be barred from ordering tests. Blanco pointed out that there are other master's level

healthcare professionals, such as respiratory therapists and audiologists, who are able to perform tests related to their specific areas of expertise.

Further, it's always been the case that the states license healthcare providers and define their scope of practice. "To expect Medicare to do something like that [for genetic counselors] is really unprecedented."

Encouraging collaboration

Gregg said that the ACMG recognizes not all doctors have genetics expertise, but he noted that genetic counselors also don't subspecialize and have varying levels of experience in a given specialty. And, while in many situations genetic counselors can help doctors identify the right tests, he noted that in complex cases the ACMG wants to ensure that counselors, doctors, and medical genetics are working together to identify the right approach for patients.

"We're not saying that the physician is all knowing … but we believe the physician should be involved at a minimum at the interpretive side, and for complex cases, probably even earlier in the test selection process," Gregg said, noting that ultimately, ACMG wants to see policies that foster a collaborative approach to patient care.

NSGC agrees that, ideally, interdisciplinary teams involving physicians, medical geneticists, and genetic counselors should be working together to determine the best course for patients, but this is simply not always possible in the current healthcare setting. Around the country, the growing demand for genetic testing and genetics expertise is necessitating innovative approaches to support services, such as via telegenetics and chatbots.

Moreover, allowing genetic counselors to work independently, "doesn’t prevent collaboration," Richardson said, "as genetic counselors are working with physicians every day to ensure the delivery of safe, efficient, and cost effective genetic services to patients and their families."

For example, within UCSF's Cancer Genetics and Prevention Program, genetic counselors and oncologists developed a framework, called the Genetic Testing Station, to address the increasing demands for germline testing and counseling. Within that effort, when oncologists identify patients who meet guidelines for germline testing, they put in a test order and send them through the Genetic Testing Station, where they can watch educational videos, give consent with genetic counseling assistants (who are trained by the counselors), and provide a sample for testing on a large multi-gene panel.

The results, once available, are shared with physicians and patients, and those with positive results receive post-test counseling either in person or over the phone based on their preference. In the pancreatic and metastatic prostate cancer setting, for example, where the National Comprehensive Cancer Network now recommends all patients get germline genetic testing regardless of family history, this approach has resulted in a 300 percent increase in timely access to guidelines-supported testing, which can potentially provide information about their inherited risks for cancer but also the course of their treatment.

The genetic counseling services offered through the Genetic Testing Station is made possible through philanthropic funding. However, from a patient access standpoint, the lack of Medicare coverage for genetic counseling is an equality issue, as far as Blanco is concerned. At UCSF's cancer division, where she is a genetic counselor, around 30 percent of Medicare patients offered genetic counseling decline it due to out-of-pocket costs, which even with discounts can be several hundred dollars.

"The expanding criteria for genetic testing makes [H.R. 3235] more important than ever," Blanco said. Historically, testing guidelines have focused on identifying younger cancer patients at risk for inherited cancers, but the latest guidelines recommend testing regardless of age for some tumor types.

"If you think about prostate cancer, more men with prostate cancer have Medicare than don't," Blanco said. "It's unethical to withhold genetic counseling services from somebody with a positive result … I view it as age discrimination that individuals with Medicare don't have [covered] access to genetic counseling."

Hooker admitted she was a bit baffled by the timing of ACMG's opposition. "It really seems counter to the needs of the healthcare system when it comes to genetic medicine," she said. "The ACMG's position is not the vision that many have in this country for genetic medicine, and it's not an evidence-based one."

Hooker, who is also VP of clinical development at the health technology firm Concert Genetics, further pointed out that as payor spending on genetic testing has gone up, counselors are increasingly playing a role in test utilization management, helping doctors identify not only which test is appropriate based on a patient's clinical and family history, but also whether that test aligns with an insurers' coverage criteria.

"Team-based care is an optimal approach for all patients," Hooker said. "But when it comes to ordering tests … all evidence points to the fact that genetic counselors can really bring their genetics expertise to the table as it pertains to selecting the right test for the patient, understanding the coverage criteria for a test, … and communicating the results to patients."

In pushing ahead H.R. 3235, NSGC has also made the case that by covering genetic counselors' services, CMS can avoid wasteful spending by ensuring patients are getting the right tests. A study commissioned by the NSGC and conducted by the consulting firm Dobson, DaVanzo & Associates projected $4 billion in potential Medicare savings over a decade if certified genetic counselors were to help patients and physicians determine which tests to order.

NSGC has further underscored its wasteful spending argument since CMS has been focused on rooting out Medicare billing fraud in genetic testing. Last year, an operation by the US Department of Justice, the US Department of Health and Human Services, and the Federal Bureau of Investigation led to the prosecution of 35 defendants for fraudulently billing Medicare for $2.1 billion for cancer genetic tests. "When we're dealing with $2 billion dollars in Medicare fraud, is [limiting genetic counselors' scope of practice] the most important discussion for us to be having?" wondered Hooker.

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