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June 27, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: File Code-CMS-5517-P; Medicare Program; Merit Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule; and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt:

The American College of Foot and Ankle Surgeons (ACFAS) is the professional society for over 7,100 board-certified or board-qualified podiatrists. Founded in 1942, ACFAS promotes the art and science of foot, ankle, and related lower extremity surgery; address the concerns of foot and ankle surgeons; and advances and improves standards of education and surgical skill. ACFAS applauds the Centers for Medicare and Medicaid (CMS) for moving towards quality care-based reimbursement and for lessening the burden of several reporting requirements. However, we have several major concerns with some provisions of this proposed regulation.

Overall Comments

Our overall concern is that this regulation will disproportionally impact podiatrists. Indeed, according to your own regulatory impact analysis, 78.0% of podiatrists will experience a negative payment adjustment.[1] The only other specialties who would receive a higher negative payment adjustment are chiropractors and optometrists at 98.4% and 79.7%, respectively. Additionally, many of our members practice in solo or small practices, which according to your estimates would also disproportionately see negative payment adjustments. These numbers are highly concerning. The College's concern is that podiatrists will quit seeing Medicare patients altogether due to the disproportionate impact these providers will face. This, in turn, will harm a Medicare beneficiary's ability to see highly qualified podiatrist. Podiatrists are the only providers who have board certification in foot and ankle surgery. There is no corresponding certification for orthopedists.

Podiatrists form an integral part to a Medicare beneficiary's care team, especially as it relates to patients with diabetes.[2] Specifically, utilizing a podiatrist as part of a care team for patients with diabetic foot ulcers helps Medicare save $3,642 per patient.[3] Utilizing a team approach, that includes podiatrists, results in a greater than

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[1] Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, 81 Fed. Reg. 28161, 28374 (May 9, 2016) (amending 42 CFR 414 and 495).

[2] L.J. Sanders, et.al, *History of the Team Approach to Amputation Prevention: Pioneers and Milestones*, 52(3 Suppl) J. Vasc. Surg. 3S-16S, (Sept. 2010).

[3] Ginger S. Carls, PhD, et.al, *The Economic Value of Specialized Lower-Extremity Medical Care by Podiatrict Physicians in the Treatment of Diabetic Foot Ulcers*, 101 J. Am. Podiatric Med. Ass'n 93, 111 (March/April 2011).

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50% decrease in amputation rates and overall healthiness in diabetic patients. Multiple studies show an increased risk in mortality the first year after having a lower limb amputation.[4] Podiatrists also help decrease falls and increase functionality in the elderly and patient population.[5] Podiatrists constitute a significant part of the primary front line physician-providers team to care for patients in chronic disease management, e.g. obesity, hypertension, osteoporosis and reduction of blood sugar in diabetics. Podiatrists achieve that by keeping patients functional on their feet with increased proprioception and balance, thereby enabling falls-prevention and functional in exercising for the minimum of 150 minutes per week as recommended by the Institute of Medicine.

What does this mean? This means that podiatrists have a great impact on keeping the Medicare population healthy through conservative and surgical means. And yet, we will experience one of the greatest negative payment impacts of all providers. The College is concerned with the negative payment adjustment for podiatrists, especially those in smaller practices, even with a showing of the positive impact podiatrist's have on a Medicare beneficiary's care.

Additionally, the College is concerned about the short timeline for implementation. Physicians would only have three or four months in which to orient themselves with the quality reporting measures. The College proposes a delay of one year for implementation of MACRA. Additionally, the College proposes that providers have six months between the time any new measures are finalized and the time in which measures must be reported.

Quality Measures

The ACFAS is a member of the Alliance of Wound Care Stakeholders ("Alliance"), a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Podiatrists are critical to the multi-disciplinary team of heath care professionals who treat Medicare patients who have chronic wounds especially diabetic foot ulcers (DFU).

In 2014, the Alliance worked with the Chronic Disease Registry (d/b/a the U.S. Wound Registry or USWR), a CMS recognized Qualified Clinical Data Registry, to create wound care quality measures. A listing can be found at https://www.uswoundregistry.com/specifications.aspx.

However, it is our understanding that while wound care practitioners can use the USWR Registry as the mechanism by which they report their mandatory 6 quality measures to CMS, none of the wound care specific quality measures themselves can be used to satisfy the reporting requirement. Instead, wound care practitioners will need to report 6 "generic" quality measures (e.g. blood pressure control, tobacco screening). The result is that important and very relevant measures like the diabetic foot examination measure, diabetic foot ulcer off-loading or the vascular screening measure cannot be used to satisfy the basic quality reporting requirements. We believe that instead of podiatrists who treat wound care patients reporting generic measures, they should be able to report quality measures that are relevant to the practice of wound care, including vital issues such as vascular screening and off-loading.

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[4] L.V. Fortington, et.al, *Short and Long Term Mortality Rates After a Lower Limb Amputation*, 46 Eur. J. Vasc. Edovasc. Surg., 124-31 (2013).

[5] B. Najafi, *The Role of Podiatry in the Prevention of Falls in Older People*, 103 J. Am. Podiatric Med. Ass'n, 452-6.

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Due to the epidemic of chronic non healing wounds as well as the escalating cost of treating them, we request that CMS allow wound care physicians to utilize the Alliance's QCDR measures to satisfy the quality measure requirements under MIPS.

Resource Use

ACFAS applauds CMS for recognizing that some patient populations require more care than others. A large number of our members work with diabetic patients. Patients with diabetes experience a higher rate of comorbid conditions, making their care much more complex. Their care is managed much differently than a healthy patient who sees a foot and ankle surgeon for an ankle sprain. Recognizing that resource use is different among patients is an important step in ensuring that providers have autonomy in managing their patients.

However, we are concerned that our doctors may be penalized for choosing a particular surgical technique or ankle implant over another. As much as foot and ankle surgery is science, it is also an art. There may be several different ways of achieving the same outcome for a patient. Surgeons may be more familiar with one surgical procedure over another because of training. Additionally, a foot and ankle surgeon may favor one ankle implant over another, due to experience and training with the implant and because the surgeon has seen more favorable outcomes with that implant. CMS should ensure that scoring in resource use accounts for these variabilities.

We appreciate the opportunity to comment on this important and historic regulation. The American College of Foot and Ankle Surgeons also offers to be a resource to you to ensure that podiatrists continue to provide quality care to Medicare patients. If we can further assist you, please contact Sarah Nichelson, J.D., Director, Health Policy, Practice Management, and Research, at (773) 444-1322 or sarah.nichelson@acfas.org.

Sincerely,

Sean T. Grambart, DPM, FACFAS
President, American College of Foot and Ankle Surgeons