September 6, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1693-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (“Proposed Rule”).

Administrator Verma:

On behalf of the Association for the Advancement of Wound Care (AAWC), I respectfully submit our association’s comments regarding the proposed rule for the Physician Fee Schedule for CY 2019.

While we appreciate the CMS’ focus on ‘Patients Over Paperwork’ and the intent to reduce the administrative burden for physicians with documentation, there are several major proposed changes in the rule regarding coding and payment that are of great concern for our members and the patients they serve.

The AAWC is a non-profit, multi-professional association of over 2,500 wound care specialized physicians, podiatrists, nurse practitioners, physical therapists, nurses, researchers, and physician assistants, along with patient and caregiver members. We treat people with traumatic, surgical, and chronic wounds such as pressure ulcers, venous, arterial and diabetic ulcers. Our members deal with the complex care and treatment(s) of patients with wounds often due to chronic systemic disease.

Our AAWC members deal with complex beneficiaries with wounds that are difficult to heal or have stopped healing. The incidence of these types of wounds is increasing as the population ages. To illustrate this further, in a recent article ¹ Dr. Desmond Bell defines the care for lower extremity wounds... “The team approach to lower extremity amputation prevention and wound management is recognized as a necessity due to the complex nature of patients afflicted with limb-threatening peripheral arterial disease (PAD) or critical limb ischemia (CLI) — the more advanced form of PAD for which there are 500-1,000 new cases seen in the U.S. per 1 million people each year.”²
Chronic leg ulcers (CLUs) affect 0.6–3% of those older than 60 years of age, increasing to more than 5% of those older than 80. CLUs are a common cause of morbidity, and its prevalence in the community ranges from 1.9% to 13.1%.\textsuperscript{3,4} It is thought that the incidence of ulceration is rising because of the aging population and the increased risk factors for atherosclerotic occlusion, such as smoking, obesity and diabetes. In the course of a lifetime, almost 10% of the population will develop a chronic wound, with a wound-related mortality rate of 2.5%.\textsuperscript{3,5} Approximately 65,000-75,000 of major amputations (above the knee and below the knee) are performed annually for CLI.\textsuperscript{6}

Nussbaum et al. analyzed the Medicare 5% Limited Data Set for calendar year 2014 and determined that chronic nonhealing wounds impact nearly 15% (8.2 million) of Medicare beneficiaries.\textsuperscript{7} Furthermore, conservative estimates for total Medicare annual spending for all wound types ranged from $28.1 billion to $31.7 billion.\textsuperscript{7}

The AAWC’s specific issues with and recommendations to the proposed rule are as follows:

**Proposed Changes to the Evaluation and Management (E/M) Services**

The consolidation of Level 2-5 E/M services, both for new [CPT® 99202-99205] and established [CPT® 99212-99215] patients, into one value without regard for the differences in the complexity between these services is of grave concern. The CMS suggests this approach will ‘help’ the physician with reduced paperwork and time by requiring only the equivalent to a Level 2 visit documentation. Documentation requirements currently differ for each E/M level because the patient’s condition and clinical needs differ for each level of care. Requiring only Level 2 documentation will not meaningfully reduce clinicians’ paperwork time, since providing Level 3, 4 and 5 care will still require thorough documentation of the patient’s condition and issues for completeness, consistency of care, and safety/risk management. Because this proposed rule would only apply to traditional Medicare fee-for-service beneficiaries, the detailed documentation requirements for 5 levels of new patients and 5 levels of established patients is still mandatory for Medicare Advantage and Medicaid beneficiaries, private payers, TriCare, Workers Compensation, etc. This will ultimately increase the time and complexity of documentation requirements for physicians.

**Reduction of Lesser Cost Service When E/M and Procedure are Performed During Same Visit**

The CMS has coupled the consolidated Level 2-5 E/M services with further reduced payment when an E/M service is provided in conjunction with a procedure on the same day. The CMS proposes to reduce the lowest cost service by 50% for both new and established patients. This change in policy undermines the intent of the “25” modifier in clinical practice. This may also result in deterring clinicians from using device-based procedures which are commonly used with wound care patients due to reimbursement insufficient to cover the cost of the device needed for the procedure. This may lead to less effective choices in care delivery that can increase time to heal, risk for infection or hospitalization.
New Add-on Codes for Additional Work

Although the CMS has proposed new E/M add-on codes for primary care providers and ‘select specialties’ to receive additional payment for the more complex patients they serve, the amounts are still inadequate for the higher Level 4 and 5 care. The add-on for inherent complexity for primary care is $5, while the inherent complexity add-on for ‘certain’ non-procedural-based care is $9. The CMS is allowing new G code GCG0X with an E/M service to describe the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches they believe are generally reported using the Level 4 and level 5 E/M visit codes rather than procedural coding.

- GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)).

This approach pays the primary care provider (e.g. wound care specialists) less than the select specialists for E/M services. Overall these add-on payments benefit providers when they provide lower level services and penalize these same providers when they provide more complex care.

### New Patient With Add-On Payments

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<th>Level</th>
<th>Current Level payments</th>
<th>Proposed Level payments</th>
<th>w/ Primary care add-on ($5)</th>
<th>w/ Certain Non-procedural based care* add-on ($9)</th>
<th>w/ extended care add-on code ($67)</th>
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### Established Patient With Add-On Payments

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<th>w/ Certain Non-procedural based care* add-on ($9)</th>
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* Limited to use by endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/ gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care.
Additionally, the new add-on code for a 30-minute prolonged E/M visit appears to be an advantage, however the $67 additional payment is only applicable for Level 4 or 5 visits. A 30-minute extended E/M service for a new patient will only result in approximately half the intended payment increase for the additional services when compared to 2018 E/M payment levels. For established patients, the resultant added reimbursement for a Level 5 service is only $12, totally inadequate for this added care.

This proposal significantly increases payment for Level 2 services, while significantly decreasing payment for the more intense, time consuming level 5 care. A predictable result of underpricing payment for complex care will be an increased frequency of ‘lesser’ visits, effectively negating any intended cost savings.

Two New E/M Codes for Podiatry Services

The proposed rule will establish two new E/M codes specifically for podiatry services reimbursed at a lower rate than comparable E/M services codes for all other physicians, despite the fact that the podiatrist may be performing the exact same service. The values assigned to these new codes are based on the average rate for CPT® codes 99201-99203 and CPT® 99211-99212, weighted by podiatric volume. This automatically assumes no podiatrist is delivering any Level 4 or 5 care. Physicians (internists, medical specialists, surgeons), DOs and podiatrists and other clinicians [NPs, PAs] could provide the same E/M service yet the podiatrist will be required to code a different and lower level E/M service code and be paid significantly less for the same involved E/M services than other clinicians.

Reducing the service level for podiatric care can negatively impact availability of podiatry services for beneficiaries. Podiatric care is essential for beneficiaries with foot wounds, diabetes, vascular disease and many other systemic conditions that impact sensation in the foot. The proposed rule targets podiatrists and unfairly segments their services from identical services provided by other providers. This proposal is discriminatory toward podiatrists and, as we understand, is illegal since it violates statute 1848(c)(6): No variation for specialists.

The impact to beneficiaries of reducing podiatric services has already been identified in the Medicaid population and reported in the study “Arizona Medicaid Study: Exclusion of Podiatric Physicians and Surgeons Adversely Impacted Diabetic Patient Health, Program Finances”. The lack of podiatric services led to a marked worsening of outcomes and cost for patients with diabetic foot infections. This study concluded that for each $1 of Medicaid program “savings” the state anticipated from the elimination of podiatric medical and surgical services actually increased costs of care by $44. In Foot in Wallet Disease: Tripped up by "Cost Saving" Reductions, researchers Skrepnek, Mills and Armstrong analyzed data for all Medicaid diabetic foot infection hospital admissions across the state of Arizona over five years (2006—2010), a time period before and after the state’s decision in 2009 to exclude podiatrists from its’ Medicaid program. The study found a significant decline in quality outcomes and higher program expenditures among those diagnosed with a diabetic foot infection, including:

- 37.5-percent increase in diabetic foot infection hospital admissions;
- 28.9-percent longer lengths of patient stay;
• 45.2-percent higher charges, and
• nearly 50-percent increase in severe aggregate outcomes.

The Arizona study complements two additional, separate studies that found that when podiatrists are administering medical and surgical foot and ankle care, outcomes are better, hospitalizations are fewer and shorter, and the health-care system saves billions of dollars annually.9,10

The AAWC considers the overall E/M proposals as detrimental to clinicians and patients, especially for the more complex work involved in treating beneficiaries with wounds often secondary to multiple systemic diseases. We believe these proposed changes will lead to unintended consequences for beneficiaries and clinicians:

- Reduce access to physician services for beneficiaries
- Require more office visits for complex conditions
- Reduce availability of podiatry services, essential for beneficiaries with wounds, diabetes, vascular disease and many other conditions that impact sensation in the foot
- Jeopardize the health outcomes for many beneficiaries
- Drive more clinicians to not accept Medicare assignment
- Decreased use of device-based procedures, due to the 50% reduction applied to either a procedure service or E/M service performed during same visit, that may be most appropriate for wound care treatment.
- Contribute to economic hardship for many primary practitioners and podiatrists
- Contribute to increased clinician burnout
- Discourage future generations from choosing the medical field.

The AAWC is intrigued by the MedPAC June 2018 Report To The Congress, in which the Commission recommends a budget-neutral option for rebalancing Medicare’s fee schedule that involves a 10% increase in payment rates for evaluation and management (E/M) services. The report stated that E/M services are not paid as well as they should be in comparison to other services such as procedures, imaging and tests because the prices of the latter are kept artificially high.

With the shift from ‘procedure-based’ care to preventative and population health and the shifting of care to the ambulatory setting, more primary care physicians will be addressing routine care for larger numbers of beneficiaries. The CMS proposed rule will drive many physicians, whose practices are based on evaluation & management, out of practice. For those who stay in practice, many will be forced to opt-out of Medicare, resulting in less availability of clinicians for beneficiary care, especially the services of a podiatrist. Access to appropriate healthcare across the US will be in jeopardy. Additionally, these changes will discourage new minds from entering medical practice.
The AAWC urges the CMS to withdraw the following proposals from the Physician Fee Schedule proposed rule, as these negatively impact beneficiaries with wounds:

1. Consolidation of E/M services Level 2-5 into one value payment method.
2. The 50% reduction for the lower cost service when an E/M and procedures are performed on the same day encounter. The AMA in their RUC process has already addressed this.
3. Establishing separate distinct E/M service codes for podiatry services.

AAWC Recommendations:

- Enact the recommendations from the MedPAC Commission (June 2018) regarding E/M services by adequately paying for the already existing levels of E/M services rather than trying to create a new system which cannot be implemented for all payers.
- Convene public forums to gain more input from all stakeholders affected before moving forward such a wide sweeping policy that negatively impact providers and patients.
- Seek a different path to address critical problem of administrative burden.
- Abandon the proposal of separate codes for podiatry.
- Continue the CMS longstanding policy of providing consistent payment to all physicians, regardless of specialty.

AAWC encourages the CMS to look for alternative ways to address the burdensome documentation requirements for clinicians in a way that does not jeopardize their livelihood or ability to use innovative procedures.

Respectfully submitted,

Dr. Tomas Serena, MD, FACS
President, AAWC


