September 10, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1691-P
PO Box 8010
Baltimore, MD 21244–1850

Submitted electronically via www.regulations.gov

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS

Dear Administrator Verma:

The American Orthotic and Prosthetic Association (AOPA) would like to take this opportunity to offer comments on proposed rule 1691-P entitled *Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS.* AOPA is the leading national trade association for patient care facilities that provide artificial limbs and orthopedic braces to patients with limb loss or orthopedic and/or neurologic problems. Its membership consists of approximately 2,000 patient care facilities throughout the United States.

AOPA's comments will be limited to those relevant to the provisions of the proposed rule that address CMS' request for information on the establishment of fees for new DMEPOS items and its request for suggestions on how to revise the

gap filling methodology that is currently used to establish Medicare fee schedule amounts for newly introduced DMEPOS items.

I. Gap-Filling History

When CMS creates a new level II HCPCS code to describe a product that is unique to the marketplace, it must create a Medicare fee schedule amount that determines the payment that will be made to providers who bill that code. Statute requires that CMS establish a Medicare fee schedule based on information from the "base year" of the Medicare DMEPOS fee schedule (1986-1987). In most cases, since new HCPCS codes represent products that are new to the market and incorporate new technology, pricing data from 1986-1987 is not available for CMS to use as a base. When this occurs, CMS relies on a procedure called gap filling in which it creates a reimbursement amount based on current information, deflates that amount using the annual change in the Consumer Pricing Index for Urban Areas (CPI-U) to 1986-1987 rates and then re-inflates the amount using the annual fee schedule increase associated with the DME or O&P Medicare fee schedule. Using deflation and subsequent re-inflation, CMS fills the "gap" between current pricing and base year pricing.

While the gap filling methodology may have made sense to fill small gaps in pricing when the statute was first written, the continued use of gap filling to span a time period of up to 30 plus years no longer makes sense as the annual increase to the Medicare fee schedule has not kept pace with the CPI-U leading to an artificial and unnecessary reduction in fee schedules based on gap filling methodology. The negative impact of the gap filling process on the establishment of accurate and reasonable Medicare fee schedules for new technologies has and will continue to influence the decision-making process of innovators and researchers who may not be able to justify the investment of research and development funds due to concerns about adequate reimbursement. This ultimately may result in a lack of access to new technologies for Medicare beneficiaries.

II. Recommendations for Improvements to the Gap Filling Methodology

AOPA believes that in order to ensure fair and reasonable reimbursement rates for new HCPCS codes, CMS must replace the archaic, non-transparent gap filling process with a fully transparent methodology that is fully transparent, involves significant stakeholder input and considers not only the cost of the device but also the clinical and professional expertise of qualified providers that are fabricating and fitting the device to best meet the medical needs of the Medicare beneficiary. AOPA offers the following recommendations to accomplish this goal.

The Statute that Created the Gap Filling Process Must be Updated to Reflect Current Pricing Methodologies

The proposed rule requests input on additional data sources and methods that could be used to estimate historic allowed charges for new technologies within the existing statutory framework. AOPA believes that this approach will not address what is clearly the root of the problem with the current methodology. Specifically, AOPA believes that the use of gap filling to address more than a thirty-year span between the base year of 1986-1987 and 2018 is simply not an efficient and reasonable method to establish current pricing. It does not address significant advances in technology, changes in the Medicare beneficiary population, and the progression of the practice of orthotics and prosthetics from an artisan-based craft to an allied health experience provided by properly educated and credentialed practitioners as well as properly accredited patient care facilities. To establish Medicare fee schedules for new O&P HCPCS codes using a pricing methodology that only considers the cost of the device without any regard to the professional service associated with the proper fit and delivery of the O&P device.

AOPA recommends that CMS propose a comprehensive change to the statute that will modernize the process of establishing Medicare fee schedules for new O&P HCPCS codes, moving away from the archaic and non-transparent gap filling process and toward a more transparent process that involves both stakeholder and beneficiary input. While AOPA understands that a change in the statute requires congressional action, it believes that the current gap filling process no longer represents a feasible methodology to truly represent the cost of providing O&P devices and the best way to modernize the system is through a change in the actual statute.

Reimbursement for Orthotic and Prosthetic Devices Should be Determined Using a Unique and Separate Process than What is Used for Durable Medical Equipment

While orthotic and prosthetic services and durable medical equipment (DME) are both reimbursed using HCPCS level II codes and claims for both benefit categories are processed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs), they are not at all similar in design, delivery, or level of professional service. In general, DME items are stocked by medical supply companies who arrange the rental or sale of the device, coordinate delivery of the device, and provide basic instruction to the patient on how to use the device. O&P devices, by contrast, often require custom fabrication and/or significant modification by properly educated, trained, and credentialed/licensed individuals who deliver an episode of care of which the delivery of the completed device is only a small component. The practice of orthotics and prosthetics has evolved into a true allied health experience in which the orthotist and/or prosthetist is a valuable member of the rehab team that works

together to ensure a proper patient experience. O&P devices are not commodity items that are simply delivered through a retail style supplier.

The current gap filling methodology used to establish Medicare fee schedules for new DMEPOS items is archaic and non-transparent for both O&P and DME items but is truly inappropriate for establishing O&P fees due to the fact that the gap filling methodology doesn't consider the value of the professional service associated with the O&P device when it is used to calculate Medicare fee schedules. O&P professionals must be recognized as the allied health providers that they are, including the consideration of their knowledge, their expertise in fabrication and fitting, and their clinical role in the patient's care, when Medicare establishes fee schedules for new item.

Current Reimbursement Rates for Similar HCPCS Codes Should be Considered When Establishing Reimbursement for New HCPCS Codes

When establishing fee schedules for newly issued HCPCS codes that represent advancements in technology in products that already have established HCPCS codes and Medicare fee schedules, CMS should use the existing fee schedule as the basis for establishing the new fee schedule. Often, ne codes are issued to describe additional features of existing products that are already represented by existing HCPCS codes. The use of current reimbursement rates as a basis to establish fee schedules for new HCPCS code is a logical option to provide adequate reimbursement for new and innovative technology.

Medicare Fee Schedules for New HCPCS Codes Must be Established Using a Transparent Process that Involves Stakeholder Input

The gap filling methodology that is currently used to establish Medicare fee schedules for new HCPCS codes is secretive, arbitrary, and does not allow for any stakeholder input. AOPA believes that to be effective an equitable, the process of establishing Medicare fee schedules for new HCPCS codes must be done through a transparent process that welcomes input from the public as well as interested stakeholders. The current process uses resources such as websites, internal and external pricelists, and product advertisements to create a base price that is then subject to deflation and inflation through the gap filling process. CMS must open the process to include public input, stakeholder feedback, and data-based resources to establish base prices that consider not only the cost of the device but also the professional service required to deliver the O&P device.

CMS Must Have a Formal Pathway to Appeal Reimbursement Decisions

Currently, when CMS establishes a Medicare fee schedule for a new HCPCS code, there is no pathway for discussion if the fee schedule was established

based on flawed information or resources. Fees may be challenged through the inherent reasonableness provisions but that is a burdensome and restrictive process. AOPA recommends that CMS establish a formal appeal process that will allow individuals or groups to formally request a reconsideration of a newly established fee schedule amount. This will allow blatant errors that may have been made through the gap filling process to be addressed and rectified immediately.

III. Flaws in the HCPCS Coding Process are Impacting Access to New Technologies

In addition to its recommendations regarding potential improvements to the gap filling methodology used to establish Medicare fee schedules for new HCPCS codes, AOPA has significant concerns regarding the process that is used to establish new HCPCS codes itself.

Research and development (R&D) for health care—whether in pharmaceuticals or in devices, represents a substantial capital commitment of resources. Companies commit to R&D based on their expectation that the increased benefits and value of new, improved technologies will be recognized via higher, justified pricing and reimbursement. If pricing is locked regardless of increases in value, companies and their investors will refrain from substantial resource commitments that offer no return on the investment. This is a basic business concept and not hard to understand.

The group with proper authority for overseeing new code requests – Medicare's HCPCS Workgroup – presents profound challenges that severely discourage the introduction of new orthotic and prosthetic technology to market, and this disincentive is reinforced by an outdated pricing policy currently under examination. In an era of unparalleled technological innovation, where FDA records demonstrate that 98% of the new medical devices applications it processes are approved as to their safety and effectiveness, the number of applications to the HCPCS Coding Workgroup has *decreased*. Over the last 5 years, O&P manufacturers have submitted only 24 applications for new products, a nearly 50% decline when compared to the preceding 5 years (49 applications).

During the same 5-year period, the HCPCS Coding Workgroup has approved only two new O&P codes, one of which – a powered ankle-foot system for lower-extremity amputees – Medicare's contractors later designated as non-covered for all Medicare beneficiaries. This tells the story that only 4% of HCPCS code applications submitted over the last five years have resulted in a new device

gaining access to Medicare beneficiaries. These numbers suggest that the obstacles to both obtaining a code and maintaining coverage for it are stifling prosthetic and orthotic innovation.

The current process for establishing new HCPC codes is slightly more transparent than it was in the past but must become more so. Currently, the only public access to the HCPCS coding process is the annual public meeting process. This process occurs after the HCPCS workgroup has made preliminary decisions regarding applications for new codes an allows applicants to make a 15-minute presentation to the HCPCS Workgroup to express their opinion on the preliminary decision of the workgroup. In addition, completing the application for a new HCPCS code is often a daunting and confusing process.

The combination of an uncertain HCPCS coding process coupled with an archaic and outdated process for establishing Medicare fees for new codes has driven many potential applicants away from the process, potentially limiting Medicare beneficiary access to important technologic advances in orthotic and prosthetic care.

Conclusion

AOPA appreciates the opportunity to provide comments on this important proposed rule and is encouraged that CMS clearly recognizes that improvements are required. In addition to the comments above, AOPA is part to and fully supports the comments submitted by the Orthotic and Prosthetic Alliance.

AOPA looks forward to working with CMS to improve the methodology used to establish Medicare fees for new HCPCS codes.

Sincerely,

Thomas F. Fise, JD
Executive Director