December 17, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Social Security Blvd.
Baltimore, MD 21244-1850

Re: Competitive Bidding Product Categories

Dear Administrator Verma:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide the following comments on CMS’s proposals to add ventilators and off-the-shelf back and knee braces to the DMEPOS (durable medical equipment, prosthetics, orthotics, and supplies) Competitive Bidding Program, when a new round of bidding is initiated in the future. AdvaMed member companies produce the medical devices and technologies that play a crucial role in allowing Medicare beneficiaries to lead healthy, productive, and independent lives in their homes and communities, thereby fulfilling the intent of Congress when it created benefits to assist those needing a wide variety of supports provided by durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Adding Various Back and Knee Braces to Competitive Bidding Program (CBP) is Premature

In a November call for public comment, CMS has asked for comments on adding numerous HCPCS codes for Back and Knee Braces to the Competitive Bidding Program. Before moving forward with this proposal that might result in perhaps two or even a single product category for braces, AdvaMed believes that CMS must first assess the nature of the products included in each of the codes for back and knee braces to determine how different they are from each other and whether some of the products described by the codes are suitable for competitive bidding. We would also ask that CMS clarify the qualifications needed for persons who would fit customized braces and other orthotics before CMS makes final decisions about expanding the scope of the CBP to include braces specified in the November announcement.

We have commented in the past that beneficiary access to quality products that patients and their physicians prefer can be compromised by the fact that individual HCPCS codes often describe a wide variety of products with very different features, characteristics, and capabilities. Because winning bidders in the CBP have an incentive to provide the least...
expensive product included in an individual code and product category, beneficiaries may
not receive the product with the features and characteristics that describe the quality
product they and their physicians prefer. We also note that the preamble in the original
2009 final rule for the CBP stated that CMS did not plan to make product categories
overly broad for purposes of bidding and we have argued that product categories be
discrete enough to ensure that beneficiaries will receive the products that best meet their
individual medical needs and health care conditions.

These same issues exist for the codes listed in CMS’s announcement proposing to add
“off-the-shelf” back and knee braces to competitive bidding. Some of the braces with the
HCPCS codes designated as off-the-shelf are not in fact off-the-shelf products and are
more like customized products requiring fitting and adjustment by a specialized fitting
professional for the braces to be fitted properly. Beneficiaries and their care outcomes
could be adversely impacted if patients attempt to fit the items themselves without the
assistance of a trained expert.

True off-the-shelf braces might be suitable for competitive bidding, but we do not believe
braces requiring customized fitting are appropriate for including in the program. To
determine which of the listed codes are truly off-the-shelf products and which are not,
AdvaMed recommends that CMS convene a group of stakeholders affected by this
proposal to work with CMS to review the codes before moving forward with the
proposed change.

AdvaMed was pleased when in September 2017 CMS decided to withdraw a proposed
rule that, among other things, would have established new training, licensure, and
certification requirements for practitioners who provide custom orthotics to Medicare
patients. As proposed, qualified practitioners (not enrolled in Medicare as a DMEPOS
supplier) would have to be licensed in orthotics, pedorthics, or prosthetics by all States in
which they practice, or, in States that do not provide licenses for those three professions,
be specifically trained and educated in those professions and certified by specified
organizations, including the American Board for Certification in Orthotics, Prosthetics
and Pedorthics (ABC), the Board for Orthotist/Prosthetist Certification International,
Incorporated (BOC), or a Secretary-approved organization that has standards equivalent
to the ABC or BOC.

As we discussed in our March 2017 comment letter to CMS on the proposed rule, the
new requirements would have no longer allowed physicians to use in their offices trained
and highly skilled but unlicensed professionals, including representatives of
manufacturers, for measuring and fitting custom orthotics. We also noted that the new
requirements disregarded the majority of State laws that do not require a license to
practice orthotics or those State laws that include exemptions to allow certain unlicensed
persons, including specially trained representatives of manufacturers, under the
supervision of a physician or other licensed health care professional, to measure and fit custom-fabricated orthotics. In addition, we pointed out that the new regulations could compromise beneficiaries’ timely access to custom products.

While we were pleased with the withdrawal of the 2017 proposed rule, the current proposal to expand the scope of the CBP leaves unanswered the question of the qualifications persons fitting customized braces would be required to have for serving Medicare beneficiaries. Before moving forward with the proposed expansion of the CBP, AdvaMed recommends that CMS first clarify requirements that it might be contemplating for the fitting of custom braces.

**Adding Ventilators to the DMEPOS Competitive Bidding Program Will Jeopardize Medicare Beneficiary Health**

Medicare beneficiaries needing mechanical ventilation for breathing support are dependent on the device to assist them with breathing and accompanying support from their DME supplier. Support services required by patients needing ventilators include maintenance and servicing of ventilators, access to a wide range of supplies that prevent complications in their condition, and ongoing clinical services and assessment from health professionals to ensure that the ventilator and related supplies continue to address the unique condition and clinical complexities of the patient.

A 2017 report by Dobson/Devanzo & Associates, *Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, Supplier Experiences* found that the Competitive Bidding Program has negatively affected beneficiaries’ access to DME services and supplies and placed strain on suppliers to deliver quality products without delay. In the case of a related product category subject to competitive bidding, the study found that “the largest number of beneficiary self-reported experiences with the DME CB program concerned access issues such as an inability to receive or access medically necessary equipment such as oxygen therapy [emphasis added], delays of medically necessary equipment, and issues concerning payment and reimbursement.” Findings such as these are especially troubling for very sick patients who need ventilators.

Especially important for patients using ventilators is the need for suppliers to provide regular and ongoing preventive maintenance and service for the device. AdvaMed is concerned that the expected lower payment rates from competitive bidding could lead to cutbacks in preventive maintenance, which in turn would have serious health consequences for patients.

A related issue is patient access to a wide variety of routine supplies that are required for use of ventilators. We have already pointed to beneficiary access problems for products subject to competitive bidding as documented in the Dobson/Devanzo study. In addition
to these broader access issues, we are also concerned that suppliers might not be adequately monitored for compliance with accreditation standards included in Appendix A of DMEPOS Quality Standards for respiratory equipment, supplies, and services—including whether they provide access on a timely basis to supplies that protect them from infection and other complications.

We note that CMS has not yet included products requiring frequent and substantial servicing in competitive bidding and we assume this reflects the challenges of ensuring adequate maintenance of equipment and access to supplies and concern within the agency that these services do not lend themselves to competitive bidding.

AdvaMed also has heard from some of our member manufacturers of other advanced medical technologies, included in the Competitive Bidding Program several years ago, that low single payment amounts have led to significantly reduced nursing and other clinical support services available to patients. These clinical support services are critical for ensuring proper use of the technologies and tracking patient progress. We are concerned that patients needing ventilators will see a decrease in critically needed health professional support services as a result of reduced payment amounts in the same way other advanced technologies have experienced under Competitive Bidding.

Concluding Recommendation

For the several reasons discussed above regarding CMS’s consideration of the expansion of the scope of the Competitive Bidding Program to include back and knee braces and ventilators, AdvaMed recommends that CMS not move forward with the proposals.

We appreciate the opportunity to provide these comments. If you have any questions, please contact Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery