August 27, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1691-P
Mail Stop C4-26-05
7500 Social Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, 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 Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments on the ESRD Prospective Payment System and DMEPOS/CBP proposed rule released July 11, 2018. 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 persons with serious kidney disease and those needing a wide variety of supports provided by durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

I. CY 2019 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

For the proposed ESRD PPS, CMS proposes to continue expanding the transitional drug add-on payment adjustment (TDAPA) in a non-budget neutral manner in order to improve the standard of care through the adoption of technological innovation for dialysis patients. AdvaMed acknowledges CMS’s commitment to foster innovation in the delivery of dialysis care and believes that a consistent approach must be taken to expand the TDAPA policies to innovative new medical devices. Medical devices, like drugs and biologicals, are an integral component of quality care for patients on dialysis. To that end, we recommend that CMS consider establishing a similar transitional add-on payment mechanism for new FDA reviewed medical devices for renal dialysis in the Final Rule.
ESRD PPS Needs A Payment Adjustment for New Medical Devices

AdvaMed is concerned that the ESRD PPS fails to effectively reflect the costs of new medical devices in renal dialysis services. Under the ESRD PPS, the ESRD PPS base rate is updated annually based only on inflation and the productivity adjustment factor. In addition, since CMS updates the ESRD PPS retrospectively, providers and ESRD facilities face a significant lag in payment and have to absorb the excess costs associated with a new device above the ESRD PPS bundled payment amount. This creates a significant disincentive for providers that want to adopt novel medical devices despite the clinical benefits for patients. This, in turn, discourages manufacturers from developing new technologies for ESRD.

Medicare is the primary payer for dialysis care for all Americans that need dialysis and plays a leading role in encouraging innovation in the delivery of dialysis care for patients with ESRD, a therapy of care where innovation has been lagging. AdvaMed believes that medical device innovation could transform the standard of care for one of Medicare’s most vulnerable patient populations and reduce costs to the healthcare system overall.

Most dialysis medical devices on the market today are reviewed and cleared by the FDA through the 510(k) pathway. From 2013 to 2017, no new devices for use in a dialysis facility were approved or authorized by the FDA under an original PMA or de novo application. This highlights the need to promote device innovation in the ESRD PPS to promote the development and submission to FDA of novel medical devices for use by dialysis clinics.

Proposed Transitional Add-On Payment for New FDA Reviewed Devices

AdvaMed believes that new and clinically superior medical devices can significantly improve the standard of care for ESRD beneficiaries and reduce costs to the healthcare system over time. We agree that CMS should not maintain the existing financial disincentives under the ESRD PPS for providers that elect to use new medical devices for renal dialysis. AdvaMed recommends that CMS should provide additional payment for such devices to foster innovation for dialysis patients.

We recommend that CMS consider establishing a 3-year transitional add-on payment mechanism for new FDA reviewed medical devices for renal dialysis in the Final Rule. A transitional additional payment could be set at the lesser of (1) the estimated costs of the new technology; or (2) the amount by which costs for a treatment using the new medical technology exceeds the costs per treatment without the new technology. AdvaMed believes that at least 3 years of transitional payment for new medical devices is an appropriate timeframe to set up system modifications and adjust business practices so that the ESRD PPS base rate can adequately reflect the cost of new technologies. We believe that any costs that are incurred by the Medicare program up-front because of new devices under the program will be offset by reduced costs in the patient’s overall cost of care through reduced hospitalizations and improved health outcomes.
At the end of the transitional adjustment period, we recommend that CMS positively adjust the ESRD PPS base rate to reflect the add-on payment in the transitional period for new devices. Failure to positively adjust the ESRD PPS base rate after the transitional adjustment period would result in a situation where providers must once again absorb the costs of new devices after the expiration of the new device add-on payment. We believe that this could discourage providers from adopting the new device at the outset or from using the device for the long-term. Both outcomes would hinder innovation and stall improvements in patient care. CMS may also want to consider additional policies to incentivize value-based care in the dialysis space as part of the long-term inclusion of technology.

**Legal Authority to Establish Device Add-On Payments to the ESRD PPS in a Non-Budget Neutral Manner for CY 2019**

AdvaMed believes that CMS has statutory authority under section 1881(b)(14)(D)(iv) to establish this ESRD PPS Device Add-On Payment in a non-budget neutral manner. Section 1881(b)(14)(D)(iv) of the Social Security Act offers CMS with “discretionary authority” to adopt payment adjustments that the Secretary determines appropriate and we believe that this authority applies to new medical devices as well. In addition, AdvaMed recommends that this ESRD Device Add-On Payment can and should be implemented in the CY 2019 ESRD PPS Final Rule given the agency’s proposal to expand TDAPA and reference to innovative devices related to the outlier policy.

AdvaMed believes that medical device innovation could significantly improve the standard of care for dialysis patients and reduce costs to the healthcare system overall. Delaying the adoption of such a payment adjustment until CY 2020 or later would unnecessarily hinder medical innovation for a significantly underserved and vulnerable patient population. Consistent with CMS authority and recent precedent, AdvaMed asks that CMS establish a transitional add-on payment to the ESRD PPS in a non-budget neutral manner for new medical devices reviewed by the FDA for CY2019.

**II. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)**

First, AdvaMed commends CMS for its decision to revisit many of the foundational decisions that have defined the basic framework of the agency’s implementation of the Competitive Bidding Program (CBP) since 2011 and to reconsider their appropriateness for ensuring Medicare beneficiary access to high quality medical technologies into the future. As you will see, we support many of the proposals in the rule for revamping the methodology used for determining single payment amounts (SPAs) under the program, but we do have some recommended revisions.
Lead Item Pricing for All Product Categories Under the DMEPOS/CBP

AdvaMed supports CMS’s recommendation of using lead item pricing in a product category and defining the lead item as that which has the highest total nationwide Medicare allowed charges of any item in the product category. Under the proposal, suppliers would submit bids only for the lead item rather than for all items in the product category. We agree that lead item pricing would greatly reduce the complexity of the bidding process and its burden on suppliers and for CMS, it would eliminate the need for item weights and calculation of composite bids based on the weights.

However, as CMS notes in the preamble to the proposed rule, this methodology can lead to distortions in single payment amounts if individual product categories are not discretely defined with items that are closely related to each other. Continuing to use product categories, especially the very large product categories established by CMS to promote one-stop shopping, may also impede beneficiary access to high quality products, simply because suppliers have not been able to submit bids for each of the diverse items in a category. The proposed rule suggests that CMS is considering breaking up large product categories, such as general home equipment, respiratory equipment, and standard mobility equipment, and AdvaMed supports this change. CMS should consider establishing sufficiently narrow categories within revised large but unified product categories. As discussed in the proposed rule, continuous positive airway pressure (CPAP) devices and their related accessories, such as masks and tubing, suggest the need for narrowly defined categories, since total allowed charges for accessories are close to the allowed charges for the CPAP device itself. Greater granularity in categories would also avoid having too many items in a single category with a lead item inappropriately determining the price for many non-lead items.

AdvaMed also recommends that CMS reconsider its policy proposal for establishing SPAs for non-lead items (1) when patients are on a therapy for a short period of time, (2) the volume of accessories/supplies can vary significantly for any given patient per month, and (3) where the proposed policy likely will result in accessory/disposable reimbursement below product acquisition costs. In these instances, we recommend using a weighted average of historical SPAs for non-lead items.

As CMS moves forward with defining product categories to be used in a new round of bidding, AdvaMed recommends that CMS use the proposed rule with comment period process before finalizing a revised configuration of product categories. Stakeholders should have ample opportunity to provide input on this fundamental aspect of the new bidding methodology.

Calculation of Single Payment Amounts (SPAs) Using Maximum Winning Bids for Lead Items

CMS proposes that the SPA for the lead item in each product category and competitive bidding area (CBA) would be based on the maximum or highest amount bid for the item by suppliers in the winning range in the CBA. The winning range of suppliers would be set based on where the
cumulative capacity of suppliers for furnishing the lead items equals or exceeds 80 percent of the demand for the lead item. The SPAs for all other items in the product category—the non-lead items—in the product category would be based on the relative difference in the fee schedule amounts for the lead and non-lead items in 2015, before the fee schedule amounts were adjusted based on information from the CBP. This methodology would replace the median bid methodology in place since the beginning of the CBP under which winning bidders could be paid less than their bids.

AdvaMed applauds CMS for proposing this change. We have argued for a variation of the proposed rule’s pivotal bid concept in comment letters and at Program Advisory and Oversight Committee (PAOC) meetings over the past several years. As CMS acknowledges, the median bid methodology has resulted in declining SPAs for several products since 2011 and continuation of this downward trend may result in insufficient suppliers accepting contracts in the future. The proposed new methodology will ensure that all suppliers in the winning range would be paid at least what they bid for the lead item or more, and this change may enhance the sustainability of the CBP into the future. We strongly support this proposal.

In addition, AdvaMed recommends that CMS revisit, in consultation with stakeholders and with every round of bidding, the relative difference in the fee schedule amounts for lead and non-lead items for each product category, given the innovation that occurs on a regular and consistent basis in the medical technology industry. We believe that this review will ensure that suppliers will be able to continue to participate in the program and will also ensure beneficiary access to the latest innovations that can improve outcomes and well-being.

Finally, we recommend that the pivotal bid used in the lead item pricing methodology be based on meeting 100 percent of projected demand, rather than 80 percent. This higher threshold will more adequately ensure that beneficiaries have access not only to the lead product within a category but all the nonlead items they need. This also provides some protection for beneficiaries, since the capacity identified by suppliers is their best estimate of the number of items they can provide to Medicare beneficiaries in a given competitive bidding area (CBA) and may be inaccurate or reflect overly optimistic projections by a bidding supplier.

Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas During a Gap in the DMEPOS CBP

In our June 14, 2018 comment letter on the interim final rule with comment period on resuming the transitional 50/50 blended rates in non-CBAs, AdvaMed recommend that the timeline for the transition’s blended rates be extended beyond July 1 through December 31, 2018 timeframe finalized in the rule and that the blended rates be applied throughout non-CBAs. We are pleased that CMS is proposing to extend the blended rate transition period through December 31, 2020 but does so only for non-contiguous and rural areas within non-CBAs. Given CMS’s finding that average volume of items and services for suppliers when furnishing those items is significantly higher in CBAs than in either non-CBAs, micro areas, or Outside Core Based Statistical Area non-CBAs, we recommend that CMS reconsider its decision not to apply the
transition blended rates and do so throughout non-CBAs. We believe that this would be a simpler and more transparent policy that is supported by CMS’s general findings on this issue to date and would minimize disruptions in suppliers available to beneficiaries.

AdvaMed also hopes the next round of competitive bidding will provide a mechanism for ensuring that payments accurately reflect the cost of serving patients in non-CBAs. One method to do so would be to use add-on payment policies like those currently used for ambulance services paid by Medicare. For ambulance services, CMS uses geographic categorization (urban, rural, super-rural) of the point-of-pickup zip code attached to each ambulance transport. Urban and rural zip codes are defined generally as those located inside (urban) or outside (rural) of a metropolitan statistical area. Super-rural zip codes are unique to the ambulance fee schedule and are defined as those which are located in a rural county that is among the lowest quartile of all rural counties, by population density.

Another approach would be to establish a special payment policy for suppliers providing service to rural beneficiaries. Currently CMS uses a special rule for rural areas for items included in more than 10 CBAs. CMS could supplement this special rule by making it more generous, and also applying the national ceiling prices in areas with a limited number of suppliers or low average volume of Medicare business. For example, the national ceiling amount could apply to areas with low volume of Medicare business or to suppliers meeting a low numerical threshold; for instance, the lowest quartile based on volume of a particular DMEPOS item or number of suppliers in an area. This would help boost payment levels in other markets, and not just rural ones. Alternatively, or in addition, CMS could also establish an add-on payment for these defined low volume or low supplier areas, based on its general approach used for rural areas in the ambulance fee schedule. This could involve increasing the base payment by a percentage amount such as 10 percent.

**Proposed Fee Schedule Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During a Gap in the DMEPOS CBP**

In the event of a future gap in the CBP before a new round of bidding, CMS proposes to adjust the SPAs used in CBAs by the projected percentage change in the CPI-U for the 12-month period after contract periods end. Given CMS’s stated concern that SPAs based on the median of winning bids threatens beneficiary access to the DMEPOS in the short terms, AdvaMed recommends that the CBA fee schedule rates be increased starting January 1, 2019 by CPI-U for the year in which they are extended plus an update for years during which there was no increase through the gap period. We also recommend 2013 as the start date to increase SPAs because this was the first year that the CBP was implemented on a nationwide basis.

**New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes**

CMS proposes to add separate and new payment classes for oxygen and oxygen equipment and would apply a budget neutrality offset to all oxygen and oxygen equipment classes and HCPCS
codes, rather than to the payment for stationary equipment and oxygen contents only. While AdvaMed appreciates CMS’s desire to reflect, with the new payment classes, the changing technologies and needs of patients for oxygen and oxygen equipment, its proposed policy to apply the budget neutrality offset to all classes of oxygen is counter-productive, resulting in higher payments for certain classes of stationary oxygen equipment and lower payments for certain portable equipment classes - at the same time as beneficiaries need and want greater access to portable oxygen. AdvaMed recommends that CMS work with all stakeholders, including patient groups, suppliers, and manufacturers of oxygen equipment, to develop new payment policies for oxygen equipment and oxygen to ensure that beneficiary needs and preferences are met in the future and that patient access to portable equipment is not compromised.

**Gap-Filling Methodology**

The proposed rule asks for comments on whether changes should be made to the gap-filling process CMS has used for establishing fees for newly covered DMEPOS items paid on a fee schedule basis and how the gap-filling process could be revised in terms of what sources or methods could be used to estimate historic allowed charges for new technologies. AdvaMed believes that the gap-filling process used by CMS for many years now should be revisited and reviewed for its adequacy in ensuring Medicare beneficiary access to innovative technologies that can lead to the highest level of functioning and well-being for patients in their homes. Further we recommend that CMS convene all stakeholders-patients, providers, and manufacturers-to discuss new approaches for a gap-filling process.

In addition, AdvaMed does have a specific recommendation to improve the existing gap-filling process. Section 60.3 of Chapter 23 of the Medicare Claims Processing Manual states that Medicare Administrative Contactors must:

- gap-fill for items for which charge data were unavailable during the fee schedule data base year using fee schedule amounts for comparable equipment, using properly calculated fee schedule amounts from a neighboring DME MAC or Part B MAC area, or using supplier price lists with prices in effect during the fee schedule data base year. Data base “year” refers to the time period mandated by the statute and/or regulations from which Medicare allowed charge data is to be extracted in order to compute the fee schedule amounts for the various DMEPOS payment categories.

Our concern is with a methodology that bases fee schedule amounts for new and innovative technologies on assumptions and decisions as to their comparability to existing equipment and also uses price lists in effect during a data base year from the late 1980s to calculate a fee schedule payment for the current year. Making decisions about the comparability of an innovative technology to existing equipment may not capture the truly innovative nature of the new technology and can then lead to payments that are inappropriately low for the item. AdvaMed believes that this process has stifled innovation in the home equipment technology arena. As an alternative to the existing process, we propose the following process for
determining single payment amounts under the DMEPOS fee schedules: If an item has never been paid under the DMEPOS fee schedules, CMS should consider the item a new DMEPOS item. CMS should use for these items invoice prices or commercial pricing to more realistically account for the cost of a new device and then use the existing methodology, deflating and applying the cumulative covered item update, to complete the gap-filling process.

**Splitting Certain Large CBAs**

The proposed rule asks for comments on whether certain large CBAs should be split into smaller-sized CBAs to create more manageable service areas. Some of our member companies have heard from supplier customers who believe that expanding the number of CBAs will increase the administrative burden of bidding, including the cost and effort of obtaining multiple bid surety bonds for the new areas rather than on bid surety bond. In addition, hospital discharge planners will face the additional burden of negotiating with multiple suppliers based on the home zip code of the Medicare beneficiary. For these reasons, we recommend that CMS not split, for the time being, large CBAs into multiple additional CBAs.

AdvaMed appreciates the opportunity to comment on the proposed rule. If you have any questions about issues raised in our comment letter, please contact Richard Price at rprice@advamed.org.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery