April 4, 2017

The Honorable Tom Price, MD
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Ave. SW
Washington, D.C. 20201

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert Humphrey Building
200 Independence Ave. SW
Washington, D.C. 20201

Re: Temporary Delay of DMEPOS Competitive Bidding Round 2019

Dear Secretary Price and Administrator Verma:

In February, the Centers for Medicare & Medicaid Services (CMS) announced a delay in moving forward with a number of major changes to the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). CMS had originally announced these changes to the public on January 31, 2017. The Advanced Medical Technology Association (AdvaMed) is writing to comment on the original announcement and to make a number of other recommendations for improving the program that we hope will be considered before CMS makes any decisions about the original announcement. AdvaMed member companies produce the medical devices and technologies that are covered under Medicare’s DMEPOS benefit. These devices and technologies play a critical role in allowing beneficiaries to lead healthy, productive, and independent lives in their homes and communities, thereby serving to fulfill the intent of Congress when it created this benefit.

On numerous occasions over the past several years, AdvaMed has written to CMS with specific recommendations for changes to the DMEPOS Competitive Bidding Program out of concern that the program has compromised Medicare beneficiaries’ access to covered DMEPOS items and, in
particular, to quality items and services that had a proven track record of improving their health and well-being. We would like to offer the following comments for your consideration during this period of delay and stand ready to share our companies’ insights and experiences for improving beneficiary health care outcomes under the program.

1/31/2017 Announcement of Major Changes to the DMEPOS Competitive Bidding Program Should Be Implemented Only Through Proposed Rulemaking with Comment Period

AdvaMed argues that the changes to the DMEPOS Competitive Bidding Program contained in the January 2017 announcement go beyond the authority of CMS to implement without first going through proposed rulemaking and comment period. The announcement included the significant changes where rulemaking should be required, including:

- Consolidating all rounds and areas included in the DMEPOS Competitive Bidding Program to date into a single round of bidding effective January 1, 2019.
- Nationwide bidding of a new product category, insulin pumps, after beneficiaries experienced significant disruptions in their access to insulin pumps in the original nine competitive bidding areas where they were first subject to competitive bidding.
- Implementation of a major new demonstration for testing bundled payments for continuous positive airway pressure (CPAP) devices and related accessories without the opportunity for public comments on the merits of the conceptual approach or its structure for protecting beneficiaries’ access to high quality products and care.

Each of these changes to the program would have potential significant adverse impact on Medicare beneficiary access to quality care and should not be implemented without formal notice of proposed rulemaking and a formal comment period for stakeholders to provide input on the proposed changes.

CMS Should Not Move Forward with Proposed Changes before OIG Releases Findings of Its Study on Impact of Competitive Bidding Program on Beneficiary Access to Quality DMEPOS Items

During 2014, Secretary Price played the central role in Congress in requesting an OIG study that would assess the Competitive Bidding Program’s impact on beneficiaries’ access to DMEPOS products, in general, and whether quality of care under the program has been compromised. Because of the Secretary’s effort, OIG agreed to do a study focused on these issues and this study has been included in each of OIG’s last three work plans. Given OIG’s commitment to the study and Congress’ interest in obtaining more and better information about the impact of the program on beneficiary health, CMS should not move forward with the major changes it had contemplated for the program before that study is completed and its findings are made available to the public.
CMS Should Focus Efforts on Stabilizing the Competitive Bidding Program to Ensure Sustainable Beneficiary Access to CPAP Devices and Accessories before Testing CPAP Bundling

Rather than testing a new payment methodology within a flawed Competitive Bidding Program, CMS should focus on reforming the program to make it more sustainable and transparent. As CMS heard on the recent Open Door Forum conference call held in response to the 21st Century Cures Act, many suppliers are no longer able to afford furnishing quality products to Medicare beneficiaries. Layering an experimental payment model on top of the unstable competitive bidding program will compound existing beneficiary access challenges. Bundling payment for equipment, supplies, and services without quality safeguards creates incentives to furnish the lowest quality equipment and reduced beneficiary support. Appropriate guardrails are needed to curb a “race to the bottom” where the care for medically complex and diverse patient populations is jeopardized. The benefits of typical episode-based bundled payment models are to improve patient outcomes by encouraging coordination of quality care across different providers and settings. However, the continuous rental CPAP model does not contain quality safeguards and only incentivizes stinting. CMS should remove CPAP bundling from the 2019 competitions, work collaboratively with stakeholders on higher priority reforms, and find other payment methods with the potential to drive behavior toward high value and compliance with therapy to put a focus on improving quality and not just reducing cost.

CMS Should Make Available to the Public Information about Its Activities to Monitor Compliance with Program Requirements and Enforcement Actions It Takes for Noncompliance

AdvaMed has called on CMS to engage in more rigorous monitoring of compliance with the statutory and regulatory requirements that apply to contract suppliers. Our recommendations have specifically asked CMS for information about compliance with and enforcement of the non-discrimination provision of law that is intended to ensure that winning suppliers offer their Medicare customers the same range of products as those offered to their non-Medicare customers. We have asked CMS to hold winning bidders accountable for making available to beneficiaries the specific products enumerated in their bids (i.e. by make, model, and manufacturer). In addition, we have also called on CMS to closely monitor contract suppliers who have had little or no experience, prior to competitive bidding, in offering and servicing a complex product subject to bidding. In addition, we have asked to see evaluations of compliance with accreditation standards during 3-year contract periods.

To date we have little understanding of the specific monitoring processes that CMS uses for monitoring compliance with various statutory and regulatory requirements or the enforcement actions the agency has taken for noncompliance. We believe that monitoring and enforcement activities can go a long way to ensuring beneficiary access to quality care under the program.
CMS Should Increase Transparency of Its Application of Regulatory Standards Used for Evaluating Bids

Problems that emerged with the selection of winning suppliers who were not licensed in the States where they would be serving Medicare beneficiaries have raised questions about the extent to which CMS and its contractor have applied regulatory standards for winning bidders and what other criteria might exist that CMS applies in making its selections. In the case of CMS’s decision to remove insulin pumps (and infusion pumps) from subsequent rounds of bidding following the Round 1 Recompete, we do not yet have an official explanation as to why CMS decided to do so. We believe that patients with diabetes were adversely impacted by the bidding selection process that awarded winning contracts to bidders who had little experience with insulin pumps, but CMS has not informed the public about why they made their original decision to remove these devices from bidding -- or why the agency has proposed to move forward with nationwide bidding for insulin pumps. Beneficiary confidence in CMS’s decision-making process for selecting appropriate contract suppliers is undermined when little information is available about all of the criteria CMS uses for selecting winning bidders and how those criteria are applied to individual applications.

With regard to financial standards, CMS publishes only the ratios, rather than the threshold metrics, and the methodology it uses across ratios for the calculation of financial merit. We believe this lack of transparency may lead to the selection of winning bidders who are not qualified to provide the items and services required under the terms of their bid and contract. CMS should apply greater transparency into its methodology to ensure uniformity in decision-making about bids and allow submission of supporting financial evidence where needed to accommodate the financial complexities of bidders of different sizes and portfolio breadth.

CMS Should Review Past Regulatory Decisions for Revision to Ensure Beneficiary Access to Quality Care

A study published in Diabetes Care by Puckrein et al., Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis, demonstrates through detailed data analysis how the Competitive Bidding Program has resulted in significant negative impact for Medicare beneficiaries’ health, in this case, persons with diabetes. The study documents the disruption competitive bidding had on beneficiaries’ access to diabetes testing supplies, leading to reduced adherence to testing, and associated increases in mortality, inpatient admissions, and cost to Medicare.

AdvaMed believes that findings such as these should lead CMS to revisit certain regulatory decisions that it has made in the past and assess whether these decisions should be revised to ensure appropriate access to quality DMEPOS products and care. As Secretary Price and other Members of Congress pointed out in their request letter to OIG for a study on the impact of the Competitive Bidding Program on beneficiary health, “[i]t would be a grave error if the bidding structure developed by the Centers for Medicare & Medicaid Services (CMS) severely reduces
access to home support services just as Congress seeks to enhance care quality through greater coordination of care, especially for patients with complex and multiple chronic conditions.”

At the time of the original proposed rule for implementing the Competitive Bidding Program, AdvaMed expressed great concern with CMS’s proposal to use the median of winning bids to set the single payment amount for a product in a competitive bidding area. CMS finalized a rule using the median of winning bids for establishing single payment amounts, and we believe that this decision has had the effect of greatly restricting beneficiary access to quality products and services. Given Congress’s interest, as expressed in the 21st Century Cures Act, for CMS to consider the “highest amount bid by a winning supplier” or clearing price, in a competitive bidding area for its methodology that adjusts payments for suppliers in non-competitive bidding areas, we recommend that CMS revisit the option of using market clearing prices to determine single payment amounts in competitive bidding. This will ensure that Medicare beneficiaries have access to a broader array of products, and higher quality products, than is the case today.

The findings of the Diabetes Care article cited above also demand immediate intervention by CMS to ensure that beneficiaries have access to quality diabetes testing systems and that the adverse impacts described in the study are not replicated in the rest of the country. OIG has shown through their reviews of the National Mail Order Program that testing systems available to Medicare beneficiaries with diabetes have changed dramatically and that the most common testing systems used by beneficiaries before implementation of the National Mail Order Program are now no longer available to beneficiaries. AdvaMed believes that negative pricing pressures of the National Mail Order Program have led to these changes and that these same pricing pressures have also compromised the quality of products available to beneficiaries. AdvaMed recommends that the National Mail Order Program be suspended to prevent further harm to beneficiaries until additional studies can be done to ensure that beneficiaries are not being adversely impacted.

In addition, AdvaMed asks once again that CMS reconsider its implementation of the 50 percent rule to require that this statutory provision apply not only to the bid of a supplier of diabetes testing supplies, but, more importantly, to the inventory maintained and offered by suppliers. Congress included this provision in statute to protect beneficiary access to the diabetes testing supplies prescribed by their physicians and did not intend that an enforcement interpretation by CMS undermine this access. We also request that CMS take stronger enforcement action to strengthen its own proposed anti-switching rule and require that suppliers of testing supplies inform beneficiaries of their rights to receive compatible with their testing systems, their rights not to be influenced to switch systems and to obtain strips from another mail order or retail pharmacy, and their rights to reject unwanted supplies.

In summary, AdvaMed requests that CMS:

- Delay the 2019 competitions to give time for the OIG study to be published and for proposed rulemaking to occur on areas of major change in the program
- Remove CPAP bundled payments demonstration from the 2019 Competition and focus on higher priority reforms to ensure appropriate access of beneficiaries to this technology
• Report enforcement actions and compliance monitoring activities to hold contracted suppliers accountable to their agreements
• Provide greater transparency on application of regulatory standards to individual bids to ensure that only qualified suppliers are selected for contracts
• Revisit certain regulatory decisions that CMS has made in the past and assess whether these decisions should be revised to ensure appropriate access to quality DMEPOS products and care, including
  o Using the bid clearing price to establish single payment amounts
  o Suspending the National Mail Order Program until further studies are completed to show that beneficiaries are not being adversely impacted by the program and applying the 50% rule to suppliers’ inventory maintained and offered to beneficiaries and increasing enforcement of the anti-switching rule.

We appreciate the opportunity to offer these comments and would be pleased to discuss them in greater detail at your convenience.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery