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AdvaMed
Advanced Medical Technology Association

August 23, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1651-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Dear Mr. Slavitt:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies provisions included in the Proposed Rule CMS-1651-P, End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). 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.

Our comments address four topics discussed in the proposed rule's provisions regarding DMEPOS and the Competitive Bidding program: surety bid bonds, State licensure, bid limits for items in competitive bidding, and determining single payment amounts for certain groupings of similar items with different features under competitive bidding.

Bid Surety Bond Requirements

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires that for rounds of bidding beginning no earlier than January 1, 2017 and not later than January 1, 2019, suppliers must submit bid surety bonds with their bids. The law specifies that the value of the bid bond be not less than $50,000 and not more than $100,000 for each competitive bidding area (CBA) in

which the supplier submits a bid. In implementing the law, CMS proposes that the bid bond value be $100,000, but solicits comments on whether to establish a lower bid surety bond amount for certain types of suppliers.

AdvaMed recommends that CMS establish the bid bond value at $50,000 for non-National Mail Order (NMO) program suppliers of diabetes testing supplies, and not at the higher level of $100,000. While Congress included the surety bid bond requirement in MACRA in order to ensure that suppliers submit bona fide bids in any future round of bidding, it did not intend that this requirement in any way compromise competition in the bidding process or reduce Medicare beneficiary access to covered items. The administrative burden for suppliers to submit bid bonds for each of the bids they would submit, together with the financial impact these bonds could have on their bottom lines, could reduce the number of suppliers submitting bids and competing to participate in the program. We also note that CMS has reported that only 8 percent of suppliers had rejected a contract offer in previous rounds of bidding. The policy solution to this problem should fit the scale of the problem—a bid bond level of $50,000 for non-NMO suppliers seems the appropriate value to deter the 8 percent of suppliers from walking away from their bids in the future.

We note our support for related CMS proposals that would establish penalties for bidding suppliers that falsify a bid bond, penalties for suppliers that do not accept a contract award or for suppliers that accept contracts and then breach contracts in order to avoid bond forfeiture. We recommend, however, that CMS consider stronger penalties than simply prohibiting participation in the current and next round of competitive bidding and suggest prohibiting participation in all future rounds of bidding.

With regard to bid bond levels for the National Mail Order program, AdvaMed recommends that bid bond values be established at much higher levels than $100,000. We believe that higher levels are justified given the national scope of business for participants in that program. In addition, we believe they are necessary, given the impact a single supplier can have on Medicare beneficiary access to diabetes testing supplies if a winning supplier declines to accept the contract it is offered.

AdvaMed also argues that current law provides CMS the authority to establish a higher level. As pointed out above, the MACRA provision on bid bonds requires a supplier to submit a bid bond for each CBA in which it submits a bid. Because NMO suppliers operate nationally, they should be held to a higher bid bond value standard than a policy which otherwise applies to a supplier operating in a single or limited number of CBAs. We understand that a supplier database indicates that many suppliers hold contracts in at least 10 CBAs, requiring that they would have to obtain $1 million in surety bonds under the proposed policy. Under this same policy, an NMO bidder would have to submit only a single $100,000 bid bond with its bid for providing diabetes testing supplies to beneficiaries throughout the entire nation. This amount is insufficient to deter the problems the bid bond requirement was intended to address. AdvaMed recommends that NMO suppliers be required to submit a bid bond of $1,000,000, a more reasonable level given the national scope of business of NMO suppliers and the need to ensure that these suppliers submit substantiated bids.

State Licensure Requirement

MACRA requires that the Secretary not award a contract to a bidding supplier unless it meets applicable State licensure requirements. CMS revises its existing regulation to conform to the new provision of law, noting that the revision does not reflect a change in policy since it has had a similar requirement in place. AdvaMed notes that while the revision may not represent a policy change, CMS should review its practice of how it actually determines whether a supplier does meet State licensure requirements.

In May 2016, the HHS Office of the Inspector General (OIG) issued a report with its findings on whether suppliers that received contracts in Round 2 of the DMEPOS competitive bidding program had met licensure requirements specified in regulation. OIG reviewed 146 suppliers about which CMS had received complaints. Of the total audited, OIG found that 69 had met State licensure requirements, 63 had not met requirements for some competitions for which they had received a contract, and 14 needed further research. Further, OIG found that the database that CMS and its contractor used when awarding contracts to suppliers was incomplete and inaccurate, in part because of variations in State licensure requirements and also because of challenges in coordinating with States to ensure that the data base was kept current.

In its report, OIG recommends that CMS work with State licensing boards to better coordinate, identify, and maintain an accurate and complete licensure database of currently required State licenses. AdvaMed supports this recommendation. The up-to-date information contained in the licensure database could then be shared with suppliers as part of the competitive bidding contractor's outreach and education activities. AdvaMed also recommends that CMS recalculate the single payment amounts when non-licensed suppliers are removed from the composite bids and rebase pricing upon suppliers licensed to do business in the CBA.

Bid Limits for Individual Items under the Competitive Bidding Program

The proposed rule would revise CMS's current policy that defines bid limits for rounds of bidding under the DMEPOS Competitive Bidding Program. Current policy limits bids to the adjusted fee schedule amounts used for non-CBAs. CMS would revise this policy to specify that bids submitted in future rounds of bidding could not exceed the fee schedule amounts established for DME, off-the-shelf orthotics, and enteral nutrition, as if adjustments to these amounts based on information from the Competitive Bidding Program had not been made. The bid limits would be based on the 2015 fee schedule amounts before adjustments made based on the Competitive Bidding Program, but updated each year by the CPI for all urban consumers reduced by the productivity adjustment. AdvaMed strongly supports the proposed policy revision, since without the change the DMEPOS benefit would be in jeopardy of becoming unsustainable and beneficiary access to covered items severely compromised.

Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items with Different Features under Competitive Bidding

AdvaMed commends CMS for advancing proposals intended to address problems of price inversion occurring as a result of the methodology used for determining single payment amounts under the DMEPOS Competitive Bidding Program. We agree that it is critical to address the unintended consequences of price inversions, since they can negatively impact beneficiary access to products with enhanced safety and functionality features needed by beneficiaries for living successfully in their homes. As CMS acknowledges, price inversion also results in beneficiaries receiving items with less functionality at a higher cost both to Medicare and the beneficiary.

While AdvaMed recognizes that the proposed alternative bidding methodology with the grouping and lead item approach may provide a solution for eliminating future price inversions, we believe that this methodology does not align with Congressional intent for the competitive bidding program, since it limits the auction process to an approach where pricing for multiple products would be driven by bids for a single product instead of having bid prices for all items. The proposed approach would also keep constant the relative price differences among items, which we believe is an unreasonable assumption because product prices could vary over time due to market factors, among other reasons.

In reviewing CMS proposals for adjusting payment amounts for products that currently have price inversions, AdvaMed recommends that CMS finalize a rule with the proposed rule's Method 1, as opposed to Method 2. Since Method 2 calculates a weighted average single payment amount using the item volume weights for groupings for similar items assigned under competitive bidding, it has the potential to compound unintended consequences with the assumption that current pricing and volume using "total nationwide allowed services" for multiple products will be balanced by a weighted average.

We appreciate the opportunity to comment on DMEPOS and competitive bidding issues of importance to AdvaMed members. If you have any questions, please contact, Richard Price at 202-434-7227 or rprice@advamed.org.

Sincerely,

Donald L. May
Executive Vice President
Payment & Health Care Delivery Policy
AdvaMed