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AdvaMed
Advanced Medical Technology Association

March 16, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., SW
Washington, DC 20201

Re: Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetic, Orthotics and Supplies by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (CMS-1561-IFC)

Dear Administrator Frizzera:

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments in response to an Interim Final Rule published in the *Federal Register* January 16, 2009, implementing changes to competitive bidding as required by MIPPA of 2008. The comments below also respond to the directive in the February 19, 2009 *Federal Register* Notice delaying the effective date of the original Interim Final Rule to April 18, 2009. That notice asked interested parties to comment again on the delay as well as substantive policy issues discussed in the original January 16th Interim Final Rule.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Rescinding the January 16th Interim final Rule/Additional Delay in its Effective Date

The preamble to the January 16, 2009 Interim Final Rule, CMS-1561-IFC, states that, for purposes of the "rebid" competitive bidding process to be used during 2009, CMS will apply the same methodologies to calculate payments and to select suppliers as it did under regulations from April 2007, and these regulations will continue to provide the framework under which it will implement the rebid program.

AdvaMed has strong concerns with CMS' decision to use its original framework and payment and product and supplier selection methodologies for DMEPOS competitive bidding. AdvaMed believes that a further delay in the effective date of the Interim Final Rule is warranted to give the new Administration ample time to reconsider alternative methodologies and polices to be applied to the rebid process. Indeed, AdvaMed believes that Congress delayed implementation of the DMEPOS competitive bidding process in order to give CMS sufficient time to reconsider the broader issues raised by the policies it chose for implementing the competitive acquisition authority established by MMA 2003 (Medicare Prescription Drug, Improvement and Modernization Act of 2003).

For these reasons, AdvaMed urges that CMS go beyond further delay of the Interim Final Rule and instead rescind this rule and publish a new proposed rule. This will give CMS an opportunity to obtain additional input from stakeholders on modifications needed to develop a more appropriate framework for a DMEPOS competitive bidding program, which supports continued beneficiary access and choice to a wide selection of appropriate DMEPOS products and technologies.

AdvaMed believes that this position is justified to allow for a process that would: (1) ensure beneficiary access to quality products and technologies, (2) provide a transparent bid application and evaluation process, (3) seek stakeholder input on certain crucial issues, such as program design, beneficiary and provider education, and an effective process for gathering and evaluating beneficiary complaints (4) recognize the importance of small suppliers and their employees, and (5) use an improved payment methodology that results in suppliers getting paid at least the amount of their bid. Each of these issues needs to be carefully considered, with necessary modifications based on input from beneficiaries and stakeholders incorporated into the new framework, before the rebid process begins. These issues are discussed in greater detail below.

Before moving forward with a Round 1 rebid, CMS should furthermore convene the Program Advisory and Oversight Committee (PAOC) to obtain input from patients, providers, and other key stakeholders on how the "rebidding" process should be modified. The deliberations of the PAOC would also serve as a vehicle for generating content for a new proposed rule on competitive bidding for DMEPOS.

What is at stake is access to products and technologies needed by a vulnerable group of elderly and disabled beneficiaries. As a June 2008 report by Sara Rosenbaum, et al., notes, over one-quarter of all Medicare beneficiaries experience some level of cognitive dysfunction, and millions lack the ability, knowledge and experience to navigate a competitive system on their own without additional assistance or education.[1] Significant changes in the competitive bidding program for DMEPOS are necessary if access to care for beneficiaries is not to be compromised.

Patient Access to the Full Range Products and Technologies

Patients with medically complex cases receive a wide array of DMEPOS products to meet their needs. A bidding process that limits the number of suppliers providing access to these technologies may threaten elderly and disabled patients' access to appropriate technology and customized DMEPOS products. The original framework for selecting suppliers contains inherent problems for assuring beneficiary access to appropriate products and technologies and these problems should be addressed before a "rebidding" process begins.

First, problems with the existing coding system used to describe DMEPOS products, the Level II Healthcare Common Procedure Coding System (HCPCS), and the use of a single code to describe a wide range of DMEPOS products, could impede beneficiary access or reduce the quality of care. For example, a winning supplier participating in the program could offer all patients a single model or brand of product that is not the most appropriate product for their individual needs or offer only one or two products at the lower end of the price range of available technologies. CMS should thoroughly evaluate the extent of groupings of diverse products into the same HCPCS code before including that code or category of products in the DMEPOS competitive bidding program.

CMS should also consider ways to bind suppliers to product offerings enumerated in their certified bids. For example, winning bidders for the original Round 1 bidding process listed specific DMEPOS products they intended to provide to Medicare beneficiaries—for each HCPCS code in a product category—as part of their bid submission process, but these commitments were not binding. Thus, as the program began, the products that were actually available were very different from those in the certified bid. This caused considerable confusion and disruption for beneficiaries, their physicians, and other referral agents who did not have authoritative and reliable information regarding the DMEPOS products offered by suppliers.

AdvaMed remains concerned that the selected numbers of suppliers may be insufficient to ensure that beneficiary demand can be met for every competitively bid product in each

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1 Sara Rosenbaum, et al., Medicare Competitive Acquisition: Implications for persons with Diabetes, The George Washington University, School of Public health and health Services, Department of Health Policy, June 18, 2008.

competitive acquisition area, and from a source reasonably convenient to all the Medicare beneficiaries living in the competitive acquisition area.

We are also concerned that at least some of the winning bidders could have relatively little or no experience in providing DMEPOS products. For certain product categories, safe and effective use frequently requires that extensive support services be provided to patients and caregivers. However, we learned that in the original Round 1 CMS selected winners for some of these product categories without requiring any prior experience with the products in the category. While prior experience may not be required for some products, CMS should require evidence that a winning bidder is able to provide both products and necessary support services within the product categories.

Furthermore, CMS should evaluate original Round 1 programs that assisted beneficiaries who were no longer able to receive services from their original DMEPOS supplier and apply lessons learned from that experience to newly established programs in order to ensure access to care. In addition, ombudsman programs must be established early in the rebid process to ensure that beneficiary complaints are properly gathered, addressed, and systematically evaluated, in anticipation that beneficiaries will see significant disruption of their existing supplier arrangements.

Transparency in the Bid Application and Evaluation Process

AdvaMed recommends greater transparency for the rebid process, including the bid application and evaluation processes. For example, final decisions regarding product categories and codes should be made at least 90 days in advance of the bidding process and consideration should be given to public comments from stakeholders regarding these categories and codes. In 2008, for example, CMS made changes in the product categories during the bidding process and had not completed specification of accreditation standards for participation, prior to the start of the bidding process.

Increased transparency is also needed in the bid evaluation process, supplier capacity calculations, and in providing information about selected suppliers and the specific services they offer. For example, CMS should more clearly state its decision criteria for evaluating bids and the weights assigned to different factors, such as a supplier's financial viability, ability to serve a particular geographic area, current and proposed product offerings, and experience in serving Medicare beneficiaries. In addition, CMS should indicate how it will verify a supplier's access to the products it claims to be able to provide, and how it will verify a supplier's financial capacity to expand to meet the patient care capacity estimates in its bid, including financial capacity to serve all the markets and product groups that it proposes.

Transparency in the criteria CMS will use for evaluating financial capacity is especially critical today, given the challenges suppliers will face in expanding their existing credit limits for growing their businesses at a time of great turmoil and uncertainty in the

nation's credit markets. Understanding the criteria that will be used is also crucial, since CMS believes that it can determine whether a supplier demonstrates financial soundness by reviewing only one year of documentation rather than three as required in the original Round 1.

Furthermore, more transparency is needed regarding CMS' evaluation of the impact of the DMEPOS competitive acquisition program, especially any changes in access to products now readily available to Medicare beneficiaries, and any impact on Medicare spending for non-DMEPOS services, such as hospital care and emergency department visits.

Transparency in Stakeholder Input

The process for stakeholder input also needs to be more transparent. One such vehicle for stakeholder input would be the Program Advisory and Oversight Committee (PAOC), which CMS should convene for input into a redesigned bidding process that would reflect reconsideration of various decisions made during the first round of bidding. The PAOC could consider and make recommendations in the following areas:

- Program design to assure access to appropriate and high quality products and technologies.
- Beneficiary and provider education, including materials, to help beneficiaries access the care they need under the new competitive bidding program.
- Special assistance to patients unable to receive DMEPOS items and related services from their regular supplier.
- An effective process for gathering, documenting, and evaluating complaints from beneficiaries.
- Criteria for evaluating bids and selecting suppliers.
- The methodology for determining payments under the program.
- Assessment of competitive bidding and its impact on overall Medicare spending (higher/lower).
- Program oversight.
- The impact the 9.5% reduction in payments for certain items might have on a new Round 1 rebid.

To reinforce transparency in PAOC deliberations on these and other issues, members of the Committee should be able to vote on specific CMS recommendations and policies, in order to indicate to CMS the specific breakdown of opinion on an issue.

Given the range of problems encountered in the original Round 1 bidding process, including lack of transparency in several key aspects of the program, CMS should revisit the process through a new proposed regulation. In this way, it will be able to provide a written rationale for decisions included in the proposed rule and will also be able to respond to all comments received.

Impact on Small Suppliers and Their Employees

AdvaMed members are also concerned that beneficiaries who receive DMEPOS from small suppliers may be most at risk in some areas, since the DMEPOS competitive acquisition program will effectively shut out many small suppliers. In addition to our concerns with patient care, this policy would lead to a significant loss of jobs for employees of these companies. We estimate that about 90 percent of the small suppliers serving the initial 10 competitive bidding areas, or about 4,000 small suppliers, were shut out of the Medicare program following the original Round 1 bidding process.

Flawed Methodology for Determining Payments for Individual Items

We believe that the methodology used for determining payments for DMEPOS items included in the original bidding process was seriously flawed and should be revised. That methodology shifted the calculation of the payment rate from the pivotal bid—defined as the highest winning composite bid and the price that all bidders have accepted—to the median of all winning bids. That change in the methodology decreased provider payment rates dramatically and further increased the potential to restrict dramatically beneficiary access to appropriate DMEPOS technologies and products. Instead, AdvaMed recommends that CMS use for the rebid process the same "adjustment factor method" that it used in the competitive bidding demonstrations.

Competitive Bidding and Diabetes Testing Supplies

AdvaMed urges that CMS move cautiously in developing a competitive bidding process for diabetes testing supplies, since any significant change in the way CMS reimburses suppliers can have significant impact on the very large population of Medicare beneficiaries with diabetes. Caution is also in order given the fact that CMS had no experience with competitive bidding for testing supplies through either of the demonstration projects.

AdvaMed believes that additional protections to ensure beneficiary access to a broad array of diabetes testing supplies are needed in the Round 1 rebid. One approach would be to apply in the Round 1 rebid a rule that was included in MIPPA for application to diabetes testing strips for competitive bidding rounds after the Round 1rebid. This rule, the 50% volume provision, would assure that beneficiaries have some minimal access to the products they have been using.

CMS should not expand competitive bidding for diabetes supplies to traditional retail markets or a national mail order program without extensive evaluation and evidence to ensure that beneficiaries will maintain access to a sufficient range of products.

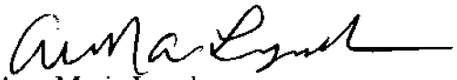
Eliminating the option for beneficiaries to obtain their preferred diabetes testing supplies from their local pharmacies would limit access to products, suppliers, and education for a vulnerable population. The introduction of these potential barriers to care may especially impact minority populations and exacerbate racial, ethnic, and socioeconomic health disparities.

Summary

AdvaMed recommends that CMS rescind the January 16, 2009 DMEPOS competitive bidding Interim Final Rule and publish a proposed rule after development of a more appropriate framework for a DMEPOS competitive bidding program that promotes continued beneficiary access and choice for appropriate DMEPOS technologies and suppliers. Alternatively, AdvaMed believes that the implementation date of April 18, 2009, should be further delayed, in order to provide the new Administration sufficient time to engage in a thorough reconsideration of the framework to be used for a rebid process. An essential part of this reconsideration process should include revised policies to ensure the protection of beneficiary access to quality DMEPOS products and services; enhanced transparency in the application and bid process; protection of small supplier participation and selection; and an improved methodology used to establish payments for competitively bid DMEPOS items. Further, CMS should convene the PAOC to obtain beneficiary, provider, supplier, and other key stakeholders recommendations regarding program modifications to ensure beneficiary access to quality DMEPOS suppliers and technologies necessary to maintain or improve health status and quality of life with minimal disruption.

Thank you for considering our comments. If you have any questions or concerns, please contact, Richard Price, Vice President for Payment and Health Care Delivery Policy, at (202) 434-7227 or RPrice@AdvaMed.org

Sincerely,



Ann-Marie Lynch