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AdvaMed
Advanced Medical Technology Association

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Re: AdvaMed Comments on Product Category Issues Raised by CMS's Announcement of the Round 1 Recompete of the DMEPOS Competitive Bidding Program

Dear Mr. Blum and Mr. Wilson:

The Advanced Medical Technology Association (AdvaMed) would like to take this opportunity to comment on several issues raised by CMS's recent announcement of the Round 1 Recompete of the DMEPOS Competitive Bidding Program. 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. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Our concerns are centered on CMS's decision to consolidate new and existing competitively bid items into fewer product categories, creating greater risks for beneficiaries as fewer suppliers with specialized expertise in certain advanced technology products will be able to provide services for them. We are also concerned that such consolidation could lead to a reduced number of suppliers submitting bids for participation in the program, including high quality suppliers that CMS has sought to maintain in the Competitive Bidding Program.

Product Categories in the Round 1 Recompete

The April 10, 2007 final rule for the DMEPOS Competitive Bidding Program defined "Product Category" as a "grouping of ***related*** items that are used to treat a similar medical condition" (Sec. 414.402). [Emphasis added.] In the explanatory preamble material accompanying the final rule, CMS stated that it had adopted this definition to clarify that it did not plan to make product categories overly broad and went on to explain that specialization at the product category level will make it easier for referral agents and other practitioners to order ***related*** products from a supplier.

We agree with CMS that the specification of product categories for bidding purposes should minimize disruption to beneficiaries, but it should not do so at the expense of quality care and patient care outcomes. In providing the Secretary the authority to determine product categories, the Congress did not instruct the agency to use this authority to unduly disturb the marketplace for DMEPOS products, including altering product distribution channels. These changes result in negative consequences for Medicare beneficiaries, as described below.

External Insulin Infusion Pumps. The Round 1 Recompete includes a new product category subject to competitive bidding--External Infusion Pumps and Supplies. This new category is comprised of 14 HCPCS codes and, as constituted by CMS, includes a broad range of products with diverse clinical uses. Suppliers of specialty pumps do not typically offer the full range of external infusion pumps listed in the new product category. As required by program regulations, however, a supplier will have to bid on all 14 codes in the category in order to submit a bid for the Recompete. An analysis of Medicare's 5 percent sample of 2010 claims finds no suppliers that furnished products in all 14 HCPCS codes, either nationally or in the nine areas included in the Recompete.

The new External Infusion Pump category includes insulin infusion pumps. Insulin pumps and related supplies are furnished to patients directly by manufacturers and a limited number of diabetes-oriented distributors. Based on an analysis of the HCPCS codes in Medicare's 5 percent sample of 2010 claims, the suppliers that provided insulin pumps to Medicare beneficiaries provided only insulin pumps and related supplies. They did not provide other items in the External Pumps and Supplies category. Because of their lack of experience providing Medicare beneficiaries other infusion pumps, they may find it particularly challenging to bid on all 14 items in the category, and, therefore, may be excluded from bidding in the Round 1 Recompete by the full-category bidding requirement.

Patient training is critical to the success of insulin pump therapy. Prior to initiating pump therapy, patients receive many hours of instruction, provided directly by experts employed by current suppliers, which are most often both the suppliers and manufacturers of the pumps. If these suppliers of insulin pumps and the experts who have gained specialized expertise working with them over the years are removed from the program, access to high quality insulin pump therapy for Medicare beneficiaries will be compromised.

Furthermore, technologies integrating external insulin infusion pumps and blood glucose monitoring systems are continuing to evolve. Including insulin infusion pumps in the larger external infusion pump category will impede this. In addition, the HCPCS code for insulin pumps, E0784, currently includes FDA class III devices, which by statute are excluded from competitive bidding.

For these reasons, AdvaMed recommends that insulin pumps and related supplies should be removed from the External Infusion Pump product category.

Transcutaneous Electrical Nerve Stimulation (TENS). The announced consolidated new product category, "General Home Equipment and Related Supplies and Accessories", includes products not previously competitively bid, including the TENS device. TENS devices are used in the treatment of patients with chronic, intractable pain or acute post-operative pain. They are not related to the other products in the General Home Equipment category, none of which are used for the treatment of pain. Nor are they used for the same medical conditions or patient populations as other items in the General Home Equipment category. For instance, TENS technology has nothing in common with a

simple commode chair or the other "general home equipment" items; nor is there any reason to expect a patient who needs TENS therapy to also need a seat lift of a powered air floatation bed. Likewise, since the other products in the General Home Equipment are not used for pain treatment purposes, it is inappropriate to include TENS devices in this category. Including them in the General Home Equipment category clearly contradicts the meaning given the term "product category" by CMS in the final Competitive Bidding Program regulation.

Additionally, like external insulin infusion pumps discussed above, TENS devices require suppliers that are specialized and experienced. Moreover, the TENS supplier must also be able to work with physicians in providing oversight of use of the product, including monitoring use during a trial period to determine that the patient is likely to derive significant benefit from use of a unit over a long period of time. Current TENS suppliers have no experience with the 60 other HCPCS codes included in the General Home Equipment category and will be unable to bid on them. This will mean their exclusion from the program and loss of their specialized experience and expertise for patients who would benefit from the technology.

AdvaMed recommends that, if CMS moves forward with its decision to include TENS in the Round 1 Recompete, it establish a separate TENS product category.

Other Issues in the General Home Equipment Category. Beyond TENS, the General Home Equipment category proposes a "catch-all" of unrelated products ranging across a broad spectrum of therapeutic and assistive functions and including hospital bed frames, support surfaces, and personal hygiene items including commode chairs, bed pans, urinals, etc. Medical technology firms that also serve as suppliers have developed specific areas of clinical expertise in more dynamic therapeutic technologies or treatments. These suppliers tend not to be involved with static, commodity-like items more commonly found in a conventional retail setting. While both types of items and products are needed by beneficiaries, grouping these disparate items into one category disproportionately and strongly biases the bidding process against medical technology suppliers that have developed considerable expertise in specific clinical areas. The loss of this group's participation will potentially diminish the process overall for beneficiaries in the context of maintaining quality, access, choice—and a competitive price.

AdvaMed recommends that CMS reconsider more broadly its announced reconfiguration and consolidation of product categories for the Round 1 Recompete and reissue a revised announcement with final product categories to be included in the Recompete, together with its rationale for its decisions to include specific items in individual product categories.

Retail Diabetic Testing Supplies (DTS). The Fact Sheet outlining the Round 1 Recompete includes the following statement:

> "CMS has elected not to include retail (non-mail order) diabetic supplies, a high-volume item with over $500 million in annual Medicare allowed charges, in the Round One Recompete. We are currently exploring options for adjusting the fee schedule amounts for retail diabetic supplies without requiring local suppliers to compete for contracts and expect to provide additional information on this issue in the coming weeks."

In response to anecdotal reports suggesting that beneficiaries have limited choice of products, the American Association of Diabetes Educators (AADE) conducted a study, *Competitive Bidding*

Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey, to investigate these claims, and to determine the range of Diabetes Testing Supplies (DTS) offered by contract suppliers to Medicare beneficiaries.[1] The AADE surveyed suppliers in the nine competitively bid areas and found that, of the nine brands that the Inspector General for the U.S. Department of Health and Human Services identified as the top mail order DTS brands (by percent utilization by Medicare beneficiaries), contract suppliers covered an average of 1.44 brands – only 16 percent.[2]

Moreover, the AADE stated that contract suppliers are misleading beneficiaries by posting inaccurate information on Medicare's website. According to the AADE, contract suppliers actually offer only 38 percent of the products that are said to be offered on www.medicare.gov.

If retail pharmacies were also subject to the single reimbursement amount paid for mail order supplies, they too could limit the range of products available and beneficiaries would be left with no options for obtaining the DTS brands that are prescribed by their physicians and they prefer. This could be especially concerning for beneficiaries who seek DTS from small, independent retail pharmacies, leaving them without access to the specific brands their physicians believe are the most appropriate for their condition.

AdvaMed recommends that CMS not adjust payments to retail pharmacies on the basis of competitive bidding rates. In light of findings regarding the impact of Round 1 on significantly reduced beneficiary access to the products they prefer, it is important that retail suppliers of DTS remain a safety valve, ensuring that beneficiaries will have immediate access to a broad range of DTS, and to the specific DTS they need.

Second, we would note that CMS has repeatedly recommended against subjecting retail pharmacies to competitive bidding rates, but may now be moving forward without ensuring that appropriate protections are in place for beneficiaries.

Obtaining Stakeholder Input for Changes to the Competitive Bidding Program

Since the beginning of the Competitive Bidding Program, AdvaMed has worked to be a responsible partner with CMS in ensuring that the program moves forward successfully to provide Medicare beneficiaries access to the most appropriate devices and technologies needed for their care. To that end, we have offered, on numerous occasions, recommendations that were intended to be constructive approaches for addressing what we perceived to be structural problems in the program that could result in negative consequences for patient care.

AdvaMed believes that the significant changes of the kind proposed for product categories in the Recompete should have been proposed and published as a notice with comment period in the *Federal Register*, prior to CMS finalizing its decisions about their configuration. A proposed rule would have provided the opportunity for meaningful feedback. This is particularly important in this case, given the absence of opportunities for stakeholders to provide comments to the PAOC and for CMS to obtain input directly from the PAOC.

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1 "Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey," (Nov. 2011)
2Office of the Inspector General's December 2, 2010 report, prepared pursuant to Section 154(d)(3)(B) of the Medicare Improvements for Patients and Providers Act, (http://oig.hhs.gov/oei/reports/oei-04-10-00130.asp).

AdvaMed recommends that CMS reestablish the PAOC for obtaining input from DMEPOS stakeholders prior to moving forward with changes to the program. We recognize that the statute establishing the Competitive Bidding Program and subsequent revisions specified a term for the PAOC. However, CMS could establish a similar vehicle for obtaining stakeholder input as CMS moves forward with an expanded DMEPOS Competitive Bidding Program. **In the absence of the PAOC, AdvaMed recommends that CMS first issue a proposed rule with comment period to allow for proper public input regarding changes in the Program, especially of the scope and breadth of those included in the announced Recompete, before finalizing its decisions to alter the program. In the case of the Recompete, CMS at the very least should have issued a notice of its planned product categories and provided an opportunity for stakeholders to comment on these product categories. This would have demonstrated that CMS was making a good faith attempt to ensure that these product categories would not have unintended consequences for Medicare beneficiaries and other stakeholders.**

Sincerely yours,

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy