March 7, 2011

Marilyn Tavenner, Principal Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Dear Ms. Tavenner,

The Advanced Medical Technology Association (AdvaMed) thanks you for the opportunity to meet with you to share our concerns regarding certain aspects of the DMEPOS competitive acquisition program as CMS moves forward with implementation of Round 2 of the bidding process. It has been our hope to communicate our concerns and recommendations before CMS issues proposed rules or program guidance for Round 2 bidding. We believe that some, though certainly not most of our recommendations, would likely require additional rulemaking.

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’s 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.

We are leaving behind this letter to provide additional detail regarding our specific recommendations for ensuring Medicare beneficiary access to high quality DMEPOS products and services throughout the competitive acquisition program.

**Independent Monitoring to Evaluate Round 1 Impact on Patient Care Outcomes**

*AdvaMed recommends that CMS use an outside independent monitor(s) to evaluate the success with which Round 1 suppliers provide the items and services beneficiaries request and require for their well-being.* While we recognize that CMS’s proposed
ombudsman program will help to identify and resolve specific problems beneficiaries may encounter under the new competitive bidding program, it is not a sufficient tool for evaluating the overall impact of the program on patient care and, more important, for identifying and defining changes that might be needed to address problems that may compromise patient care outcomes.

AdvaMed believes that an independent monitor(s) can also play a central role in ensuring patient access to high quality DMEPOS products and services by assisting CMS with finding solutions to operational problems before implementation of Round 2 moves forward. We recommend that the independent monitor(s) evaluate, at a minimum, the following areas:

- **Hold Bidders Accountable**—Winning bidders must be held accountable for making available to beneficiaries the specific products enumerated in their bids (i.e. by make, model, and manufacturer). In 2008, beneficiaries did not learn that the products actually available from certain suppliers were very different from those in the suppliers’ certified bids until the program began. The failure to communicate this information caused considerable confusion and disruption for beneficiaries and their physicians. Products are not always interchangeable and Medicare beneficiaries are often prescribed specific brands of products to meet their specific medical needs; this is particularly true in the case of diabetes testing supplies.

- **Range of Products**—Winning bidders should also be monitored for their compliance with the non-discrimination provision in Medicare law requiring suppliers to offer their Medicare customers the same range of products as those offered to their non-Medicare customers. Medicare beneficiaries should have access to the same products and services as non-Medicare patients.

- **General Performance**—Suppliers should also be evaluated as to whether they have appropriate facilities with clearly defined business hour schedules and after hour/emergency services, inventory of products enumerated in their bids, financial solvency, and staff, trained and certified, available and in place to meet the capacity goals stated in their bid documentation.

- **Patient Education**—Contract suppliers should also be held accountable for educating patients on a product’s use in addition to being able to fully service the product when these are essential components of the covered service. In cases where the patient is impaired and/or unable to operate the device, the supplier should help accommodate the need to educate a caregiver.

- **Quality Standards Compliance**—It is not enough that contract suppliers obtain accreditation and satisfy DMEPOS quality standards. CMS should continuously monitor contract suppliers to ensure ongoing compliance with the standards required for the particular products for which they have been designated as winning bidders, especially when they have had little to no experience prior to
competitive bidding in actually offering and servicing a complex product to beneficiaries. Contract suppliers should also be monitored for having a clear process for reporting adverse events as required by FDA.

- **Additional Quality Standards**—The independent monitor should also make recommendations as to whether additional quality standards are needed to assure patient access to quality products and services. (See below.)
- **Anti-Switching Rule**—Contract suppliers should be monitored for their compliance with the anti-switching policy finalized in recent regulations (see below).
- **Product Access**—Contract suppliers should be monitored as to whether they compromise beneficiary access to appropriate DMEPOS technologies, as well as innovative technologies, determined to be medically necessary by beneficiaries’ health care providers (see below).

The independent monitor should begin oversight and evaluation of these and other areas that define quality of care as soon as possible, but no later than March 1, 2011. The monitor should also issue quarterly reports on its findings and make these reports available to CMS, Congress, OIG, and the public.

**Evaluation Before Further Action**

*AdvaMed recommends that CMS thoroughly assess Round 1, including the findings of the outside monitor recommended above, to inform the structure and characteristics of the bidding process before moving to Round 2.* With this recommendation, AdvaMed is not suggesting that the competitive bidding program statute be amended. Nor are we suggesting that CMS delay Round 2 beyond the anticipated implementation date of January 1, 2013. We are simply recommending that actual experience with Round 1 should inform the structure of the program going forward before CMS makes decisions about what that structure should be, and that the independent monitor’s findings be given an opportunity to define changes and adjustments that may be needed to the program to ensure that beneficiaries have access to the highest quality of care. The independent monitor’s evaluation should include an assessment of how clinical outcomes change over time for patients served under the program, and comparing these with outcomes for persons not in competitive bidding areas. In this regard, it is not sufficient simply to survey patients about their satisfaction with the care they receive under the competitive bidding program, since they may not have a satisfactory understanding of what constitutes good products and service. In addition, prescribers of DMEPOS included in the program should be surveyed over time as to their experience with the program and its impact on patient health.
Payment Policy Improvements

In September 2010, 165 economists and auction experts sent a letter to Congressman Pete Stark identifying four problems with the bidding process used by CMS for determining single payment amounts for DMEPOS items included in Round 1. This letter was subsequently forwarded to CMS. In brief, the problems they identified were as follows: (1) bidders are not bound by their bids; (2) the system sets reimbursement amounts at the median of the winning bids, rather than the clearing price at which supply and demand balance; (3) the current system selects winners using composite bids, which are an average of a bidder’s bids across many products, weighted by government demand estimates, with the result that prices for individual products do not align with costs; and (4) quantity standards and performance obligations are unclear in the bidding process.

Advamed is concerned that the current methodology for determining the single payments amounts results in unreasonably low payments that will severely restrict beneficiary access to appropriate and quality DMEPOS technologies and services. Advamed recommends that CMS return to the methodology used for the competitive bidding demonstration projects. These demonstrations used an “adjustment factor method” to determine Medicare payment amounts. Under this methodology, an adjustment factor was calculated for each winning bidder, based on the relationship between the pivotal composite bid and each supplier’s composite bid. This ensured that each winning supplier received at least as much as they had bid for a given product category.

Additional DMEPOS Quality Standards

Contract suppliers must be accredited as meeting DMEPOS quality standards in order to participate in the competitive bidding process. The existing accreditation standards set out requirements that all suppliers must meet, as well as additional and unique standards that apply to certain DMEPOS products. Two examples of technologies to which additional standards apply are oxygen and complex rehabilitative wheelchairs.

In 2010, the Food and Drug Administration published a white paper outlining concerns about several categories of complex therapeutic devices which have migrated from institutional settings into the home. While the FDA stated that these products bring value to patients and payers, they also noted increased safety risks if suppliers of these products do not adequately educate and support providers, patients and family caregivers. Negative Pressure Wound Therapy (NPWT) products were specifically listed as one of these categories. For this reason, Advamed recommends that CMS incorporate into the existing standards additional, unique standards for negative pressure wound therapy. Such standards will begin to ensure that only those bidders qualified to provide the full range of services associated with a particular technology care are able to submit bids at the onset of a new bidding process.
Additionally, it will be important to have an independent monitor determine whether suppliers with winning bids meet all relevant accreditation standards as they deliver service to beneficiaries under any round of competitive bidding. Just as critical for complex therapeutic categories such as NPWT, the monitor should evaluate comparative clinical outcomes before and after implementation to assess whether there are unintended adverse consequences of the competitive bidding process.

**Anti-Switching Rule/Diabetes Test Strips**

Under final regulations that become effective January 1, 2011, CMS will establish an anti-switching rule that will prohibit contract suppliers of diabetic testing strips from influencing or incentivizing beneficiaries to switch the brand of glucose monitor and testing supplies they are currently using. Suppliers will be required to furnish the brand of testing supplies that work with the blood glucose monitor that the beneficiary and/or clinician selects as the most appropriate. If a contract supplier does not stock a specific product or is out of inventory of a specific product they carry and which the beneficiary needs, the beneficiary can then go to any other contract supplier to see if they carry the product they need in stock. If a beneficiary needs a blood glucose monitor for the first time, or need to replace their existing monitor, and neither the beneficiary nor their physician has determined which brand or type of monitor to obtain, the rule allows the beneficiary to continue to ask the supplier for assistance in selecting a monitor and the supplier would be required to show the full range of products.

AdvaMed supports the general framework for CMS’s anti-switching rule. We agree, for example, that a contract supplier must not furnish information about alternative brands of diabetes test strips unless a beneficiary requests such information. We are concerned, however, that the finalized anti-switching policy alone is inadequate for assuring that suppliers do not exert undue influence in patients’ selection of diabetes test strip products. **AdvaMed recommends that CMS prohibit contract suppliers from furnishing information about alternative brands to the beneficiary unless the beneficiary requests such information. Furthermore, AdvaMed recommends that CMS adopt the following additional mechanisms for ensuring compliance with the anti-switching policy:**

- A requirement that suppliers must first to obtain a physician authorization before switching a beneficiary’s products;
- An independent monitor should evaluate whether contract suppliers are complying with the anti-switching policy.

AdvaMed also asks that CMS clarify the application of its anti-switching policy in instances where products must be switched because of new FDA standards, discontinuation of products, or damaged products, while at the same time protecting the need of patients for choice and education regarding available product options. For example, if a patient accidentally damages a particular DMEPOS product, this should not
be viewed as legitimate grounds for a mail order supplier to subtly coerce the beneficiary to switch to an entirely different brand of product when the simple replacement of the damaged product—with the same make and model—would suffice.

**Special Rule in Competition for Diabetic Testing Strips (50 Percent Rule)**

*AdvaMed recommends that CMS require suppliers to demonstrate compliance with the 50 percent rule on a contractual term basis, and not just as a condition for bid submission and review.*

CMS should further enhance the 50 percent rule by requiring that suppliers comply with the rule on an ongoing basis, and not just as a condition in the bid submission. Currently, it appears suppliers need only make an initial demonstration that they are meeting the requirement, but that they can then offer a more limited range of products once they become a contract supplier. This is not consistent with congressional intent in the legislation, and should not be the standard in the regulatory implementation. We recommend that CMS ensure that contract suppliers carry a sufficiently diverse array of testing strips throughout the duration of the CBP contract period to ensure beneficiary access. As noted above, AdvaMed also recommends that CMS use an independent monitor for evaluating compliance with the 50 percent rule.

**Grandfathering Rules**

Under the existing grandfathering rules, beneficiaries who were renting DME, oxygen, and oxygen equipment prior to the start of competitive bidding period from a supplier who did not win a contract may continue to rent the equipment from that non-contracted supplier if the supplier chooses to become a grandfathered supplier. The grandfathered supplier agrees to payment of the single payment of the single payment amount established by the competitive acquisition process. *AdvaMed recommends that CMS extend the grandfathering option to suppliers of enteral nutrition, in order to minimize disruptions to care that are likely to accompany the phasing in of competitive bidding.* Since the grandfathering option is not currently available for enteral nutrition suppliers, all enteral patients of non-winning suppliers will have to find new suppliers upon the implementation of the competitive bidding program. Many enteral patients had difficulty locating new suppliers during the brief operational period of the original Round 1. To avoid future problems and to ensure that beneficiaries continue having access to high quality services and equipment, patients should have the option of continuing to receive enteral nutrition from experienced suppliers with which they have established relationships. This option would provide a safety net for critically ill patients, and, at the same time, would not result in increased Medicare spending, since suppliers under the grandfathering rules would have to accept the single payment amount in their areas.
Conclusion

AdvaMed greatly appreciated the opportunity to meet with you to discuss issues in the DMEPOS competitive bidding program of concern to our member companies. We look forward to working with you and CMS staff to help move forward our specific recommendations for ensuring Medicare beneficiary access to high quality care under this program.

We are available to work with you and your staff to discuss how these matters can be resolved. Should you or your staff have any questions, please contact Richard Price at rprice@advamed.org or (202) 434-7219.

Sincerely,

Ann-Marie Lynch