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**AdvaMed**  
Advanced Medical Technology Association

**HOUSE SMALL BUSINESS  
SUBCOMMITTEE ON  
INVESTIGATIONS AND OVERSIGHT**

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**STATEMENT BY**

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**ON BEHALF OF  
THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)**

We thank the Subcommittee for holding this important hearing today on Medicare's implementation of the competitive acquisition program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

As you may know, AdvaMed represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than \$30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the \$86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the \$220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of our populace, in 2006 the industry employed 357,700 workers; paid \$21.5 billion in salaries; and shipped \$123 billion worth of products. The national impacts of this industry were even more substantial. Taking into account the national multiplier impacts, the industry created (direct plus indirect plus stimulated impacts): 1.96 million jobs; payrolls that totaled \$93 billion; and \$355 billion in shipments/sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intensive competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible. Innovations specifically within the DMEPOS sector allow patients to transition to less costly home care settings, where treatment continues while enabling them the independence of living in their home.

### **Patient Access to Innovation**

Access to quality DMEPOS and related services can often mean the difference between a patient being able to remain in their own home or being admitted to the more expensive (and in consequence higher cost to the Medicare program) treatment care of a nursing home or hospital. DMEPOS products enable providers to give essential care to many of the frailest and sickest Medicare patients.

The medical device industry has developed a wide array of DMEPOS products to meet the patient care needs of many complex conditions. A bidding process that limits the number of suppliers providing access to these technologies may also threaten patients' access to better-technology and customized DMEPOS products. Most importantly, it limits the ability of smaller manufacturers to compete to supply these innovative and unique technologies.

To deliver this value to patients, our industry invests heavily in research and development (R&D). Today, our industry leads global medical technology R&D, both in terms of innovation

as well as investment. The level of R&D spending in the medical devices and diagnostic industry, as a percent of sales, more than doubled during the 1990s – increasing from 5.4% in 1990 to 8.4% in 1995 and over 11% last year. In absolute terms, R&D spending has increased 20% on a cumulative annual basis since 1990. Our industry’s level of spending on R&D is more than three times the overall U.S. average. If competitive bidding reduces the prices for DMEPOS products to a point where the ability to reinvest in additional R & D is eliminated, the patient will suffer. CMS must take this into consideration with necessary safeguards in development of the competitive bidding program for DMEPOS.

### **Medicare’s Competitive Acquisition Program**

As you know, Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), included provisions that require the Centers for Medicare & Medicaid Services (CMS) to implement a competitive acquisition program for DMEPOS. This new program transitions reimbursements for DMEPOS from the current fee schedule to amounts that are set through a bidding process between CMS and suppliers in defined Metropolitan Statistical Areas (MSAs). In doing so, the new payment system changes Medicare’s basic premise from beneficiaries having access to “any willing provider” to a selection process that over time will significantly reduce the number of accessible suppliers.

The Balanced Budget Act of 1997 (BBA) authorized CMS to conduct five, three-year competitive bidding demonstration projects. CMS only conducted demonstrations at two sites (Dade County, Florida and San Antonio, Texas), testing only eight products. The details of designing and implementing these projects were largely left to CMS.

Given this very limited test of competitive bidding, the medical device industry – companies both large and small – joined others to voice concerns about the potential impact for innovators and the patients for whom we develop the devices. We recommended a number of provisions during consideration of the MMA to assure beneficiary access to DMEPOS products and related services prescribed by their physicians, including:

- A patient advisory and oversight committee to allow stakeholders to provide input during design and implementation of the program;
- An open and transparent bidding process;
- A requirement that multiple suppliers be accepted as “winning” bidders to ensure there are sufficient numbers of suppliers to meet patient needs;
- Provisions to ensure beneficiaries have access to new technologies that come in to the marketplace after the program begins;
- Safeguards to ensure beneficiary choice is preserved;
- Methods by which to monitor and evaluate the program and its impact on beneficiary access, quality of care, market competitiveness, and patient satisfaction.

The MMA did require the establishment of a Public Advisory and Oversight Committee (PAOC) to allow for stakeholder discussions on the implementation of the program. We believe it has been a helpful tool during the implementation process, but we are concerned that a number of our other recommendations are still not being addressed. We continue to advocate for changes to the program as it is being implemented to ensure continued patient access to the array of life-enhancing and life sustaining technologies they may need.

## Recommendations for Improving the Competitive Acquisition Program

Due to its direct impact on daily patient care, the DMEPOS competitive acquisition program must be carefully implemented with significant attention to detail, especially the impact on patients. We appreciate your willingness to listen to our concerns and to work with manufacturers and suppliers to ensure that Medicare beneficiaries continue to receive high quality DMEPOS. We recommend the following actions be taken by Congress or CMS:

- **Report to Congress.** The MMA requires a report to Congress by July 1, 2009 on the competitive acquisition program. We request that the PAOC be allowed to make recommendations to CMS on report parameters, and we believe these parameters should include clinical outcomes, quality measures, measures to assess beneficiary access to the range of affected technologies, potential impact on other Medicare services (such as hospitalizations) as a result of the competitive bidding program, specific impact on cost-savings, and the impact on number the of DMEPOS providers within MSAs.

Let me relate the need to oversee quality issues based on my past experience with another competitive bidding program. My company strives to manufacture high quality devices that meet the special needs of individual patients. We participated in a competitive bidding program that previously evaluated devices through a comprehensive review of device quality and features. Unfortunately, that program now focuses solely on cost savings for this category of devices. The quality of the devices is no longer assessed. Now I'm concerned patients' needs aren't being met.

- **Required Bidding Process for Expansion.** We have strong concerns about CMS' ability to use bid amounts determined in setting payments in one MSA to set rates in another MSA. Patient needs and costs for providing care and technologies are not the same in every MSA. If this program continues, CMS should be required to conduct a separate bidding process in each and every MSA in order to ensure that the payment amounts used by Medicare reflect local market conditions.
- **Small/Rural MSA Exemption.** Many are concerned that small and rural MSAs would not have enough suppliers who would be able to provide for the entire MSA, or network to provide for the entire MSA, to meet patient needs. We recommend that small and rural MSAs be exempted from this program.
- **Public Meeting on Categories/Codes.** Product codes used by CMS are too broad and inconsistent to adequately describe products with diverse and broad ranges of quality, functionality, technology, and clinical utility. Beneficiaries may not have access to a full range of products if the accepted bidding amount does not reflect the varying costs of the range of products. Also, we believe it was most unfortunate that CMS found it necessary to make changes in the product categories even while the bidding process was underway, rather than having done so beforehand. This could have been avoided if stakeholders had been given the opportunity to comment on product categories and codes in advance.

We urge CMS to allow for such public comment on the categories and codes being bid and such potential problems. Furthermore, to make public the list product categories to be bid in each future bidding cycle and the codes proposed for each product category. CMS should

then convene a meeting of the PAOC to discuss the categories and codes and accept written comments, which must be taken into account in making final determinations. CMS should also be required to provide a rationale for final determinations and respond to comments received.

- **Savings Certification.** Many are concerned that the focus of the competitive acquisition program is financial savings with little consideration of the impact on quality of care and patient choice. If CMS expands the program to additional MSAs, the agency should have to certify a net savings per category to the DME fee schedule of over 10%. The net savings must include accurate deduction for administrative costs associated with the program. We note that in CMS' Final Report to Congress: Evaluation of Medicare's Competitive Bidding for DMEPOS in 2004, the report stated that "the project saved significant expenditures, nearly 20 percent overall in each site." Thus, a 10% net savings requirement should be reasonable.
- **Grandfather Enteral Nutrition Patients.** There are provisions in the program currently to "grandfather" patients who receive DMEPOS items for which payment is made on a rental basis, thus allowing them to maintain current services for the duration of the rental contract. These grandfathered products require frequent and substantial servicing, and the grandfathering policy applies to capped rental items, like oxygen. However, enteral nutrition patients, who are fed via a pump, are not included in this grandfathering process. These patients are frail and elderly – often stroke patients – who have been receiving their pump and enteral nutrition supplies for long periods of time and have developed trusting relationships with a particular supplier. We believe that these rental contracts should also be honored and grandfathered as well since enteral nutrition pumps are covered under the prosthetic device benefit and meet the criteria outlined for exemption.
- **Antitrust Protection for Potential Competitive Bidding Networks.** To ensure that small suppliers are able to form networks and participate in the program, we recommend that the Department of Justice provide limited antitrust immunity be accorded to DMEPOS suppliers that meet the regulatory criteria be given.
- **Appeals.** The adoption of this new program is complex, and its initial steps have been met with some difficulty. To ensure fairness and transparency, we recommend that CMS provide written explanations/remedies for providers whose application for participation was rejected due to technical reasons (i.e.: non-bid price related issues).

## Conclusion

Thank you again for holding this important hearing. As an industry that thrives from innovation and relies upon the energy of its significant small manufacturers, we greatly appreciate the opportunity to raise awareness of the concerns about the impact of the new competitive acquisition program on Medicare and their access to innovative products. We look forward to working with this Committee on ways to ensure all manufactures remain able to offer existing quality product and develop new and innovative DME for this critical sector of the population.