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ON

MEDICARE'S DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM: HOW ARE SMALL SUPPLIERS FARING?

BEFORE THE

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Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How Are Small Suppliers Faring?
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Chairwoman Ellmers, Ranking Member Richmond, and distinguished members of the Subcommittee, I am pleased to be here today on behalf of the Centers for Medicare & Medicaid Services (CMS) to discuss the competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). This important initiative is reducing beneficiary out-of-pocket costs and program outlays, while ensuring continued access to high quality DMEPOS items and services, establishing Medicare's DMEPOS payments based on competitive market pricing, and helping combat supplier fraud. On January 1, 2011, CMS launched the first phase of the program in nine major metropolitan areas for nine product categories. I am pleased to report that in its first year of operation, the DMEPOS competitive bidding program saved the Medicare fee-for-service program approximately $202.1 million, and according to CMS's Independent Office of the Actuary, the program is projected to save the Medicare Part B Trust Fund $25.7 billion between 2013 and 2022, with an additional $17.1 billion in savings for beneficiaries during that period.[1] CMS has worked to ensure that small suppliers remain an important part of the DMEPOS program, and I am pleased to report that small suppliers (defined as those with annual gross revenues of $3.5 million or less), made up 51 percent of the winning suppliers.

Overview and Program History

CMS is the largest purchaser of health care in the United States, serving more than 100 million Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. Each year, DMEPOS suppliers provide items and services, including power wheelchairs, oxygen equipment, walkers and hospital beds, to millions of Medicare beneficiaries. In 2010, before competitive bidding took effect, combined expenditures (including beneficiary cost-sharing) were approximately $14.3 billion for DMEPOS. About 15.5 million Medicare beneficiaries used DMEPOS in 2010.

[1] *Competitive Bidding Update—One Year Implementation Update*, April 17, 2012: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf

The current Medicare DMEPOS benefit is plagued by an obsolete pricing methodology, grossly inflated prices, and a well-documented proliferation of fraudulent practices fueled by these inflated prices.[2] With the exception of the 9 areas where competitive bidding is now in effect, Medicare Part B currently pays for DMEPOS items and services using fee schedule rates for covered items. In general, fee schedule rates are calculated per the statute using historical supplier charge data from more than 20 years ago that are often much higher than market prices. Relying on historical charge data has resulted in Medicare payment rates that are often higher than prices charged for identical items and services furnished to non-Medicare customers. Medicare beneficiaries and taxpayers bear the cost of these inflated fee schedule rates. The Department of Health and Human Services' Office of Inspector General (OIG)[3], the Government Accountability Office (GAO), and other independent analysts have repeatedly warned that the fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or customers who purchase these items on their own. These inflated prices in turn increase the amount beneficiaries must pay out-of-pocket for these items.

To provide greater value to the Medicare program, beneficiaries and taxpayers, Congress established the Medicare DMEPOS Competitive Bidding Program in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173). The program was modeled after the successful demonstration projects in Polk County, Florida and San Antonio, Texas between 1999 and 2002, which resulted in 20 percent savings for Medicare and beneficiaries without any negative impact on access to equipment or quality of care for beneficiaries. Under the MMA, the DMEPOS Competitive Bidding Program was to be phased into Medicare so that competition under the program would initially begin in 10 metropolitan statistical areas (MSAs) in 2007. Consistent with the statutory mandate, CMS conducted the Round 1 competition in 10 areas and for 10 DMEPOS product categories, and implemented the program on July 1, 2008, for two weeks. The program's single payment amounts resulted in a

[2]See *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011* for examples of DME related fraud: http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf

[3] See, for example, *Comparison of Prices for Negative Pressure Wound Therapy Pumps*, OEI-02-07-00660, March 2009; *Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services*, OEI-04-07-00400, August 2009; *Medicare Home Oxygen Equipment: Cost and Servicing*, OEI-09-04-00420, September 2006.

projected savings of approximately 26 percent compared to the traditional Medicare fee schedule. This indicated the potential for substantial savings for Medicare beneficiaries and taxpayers upon full scale implementation of the program.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) delayed the start of the program. MIPPA terminated the Round 1 contracts that were in effect and reinstated fee schedule payment rates, required rebidding of the first round at a later date, and imposed a nationwide 9.5 percent payment reduction for all Round 1 items in 2009. MIPPA required competition for Round 2 of the program to be conducted in 2011 in 70 additional MSAs. In addition to the delay, MIPPA mandated certain changes but maintained the competitive bidding program. The Affordable Care Act (P.L. 111-148 and P.L. 111-152) subsequently expanded the number of Round 2 MSAs from 70 to 91 and mandates that all areas of the country be subject either to DMEPOS competitive bidding or payment rate adjustments to the fee schedule using competitively bid rates by 2016.

CMS implemented a variety of operational improvements to the program prior to rebidding the first round as required by MIPPA. CMS incorporated all of the program improvements required by MIPPA, including the "covered document" review process. This process gives bidders who submit their proposal by the covered document review date the opportunity to be notified of missing financial bid documents and submit the missing documents. In addition, CMS implemented a number of other important improvements based on lessons learned from the 2008 bidding process, feedback from stakeholders, and advice from the Program Advisory and Oversight Committee (PAOC). Some examples of these key operational improvements include an upgraded bidder education program completed prior to the opening of the bid window; a new and improved online bidding system; and enhanced bid evaluation processes such as a comprehensive upfront licensing verification process, a more rigorous bona fide bid evaluation process to verify the sustainability of very low bids, and increased scrutiny of expansion plans for suppliers new to an area or product category.

Considerations for Small Suppliers

In developing the competitive bidding program, CMS worked closely with suppliers, manufacturers and beneficiaries through a transparent public process. This process included many public meetings and forums, the assistance of the PAOC (which included representation from the small supplier community), small business and beneficiary focus groups, notice and comment rulemaking, and other opportunities to hear the concerns and suggestions of stakeholders. As a result, CMS' policies and implementation plan pay close attention to the concerns of these constituencies, in particular those of small suppliers.

During the implementation of this program, CMS adopted numerous strategies to ensure small suppliers have the opportunity to be considered for participation in the program. For example:

- CMS worked in close collaboration with the Small Business Administration to develop a new, more appropriate definition of "small supplier" for this program. Under this definition, a small supplier is a supplier that generates gross revenues of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue rather than the previous standard of $5 million. We believe that this $3.5 million standard is representative of small suppliers that provide DMEPOS to Medicare beneficiaries.
- Further, recognizing that it may be difficult for small suppliers to furnish all the product categories under the program, suppliers are not required to submit bids for all product categories. The final regulation implementing the program allows small suppliers to join together in "networks" in order to meet the requirement to serve the entire competitive bidding area.
- In addition, to help ensure that there are multiple suppliers for all items in each competitive bidding area (CBA), each bidder's estimated capacity, for purposes of bid evaluation only, was limited to 20 percent of the expected beneficiary demand for a product category in a CBA. This policy ensures that multiple contract suppliers for each product category were selected and that more than enough contract suppliers are selected to meet demand for items and services in area. For most areas and product categories, the result of this policy will be an increase of the number of contracts awarded by CMS beyond the statutory threshold of two contracts per product category per CBA.

- The financial standards and associated information collection that suppliers must adhere to as part of the bidding process were crafted in a way that considers small suppliers' business practices and constraints. We have limited the number of financial documents that a supplier must submit so that the submission of this information will be less burdensome for all suppliers, including small suppliers. We believe we have balanced the needs of small suppliers and the needs of beneficiaries in requesting documents that will provide us with sufficient information to determine the financial soundness of a supplier.

The regulation also established a 30 percent target for small supplier participation in the program.

Round 1 Rebid

With improvements and protections in place, CMS implemented the Round 1 Rebid of the competitive bidding program in nine MSAs on January 1, 2011, covering nine DMEPOS product categories.[4,5] CMS awarded 1,217 DMEPOS competitive bidding program contracts to 356 suppliers. All contract suppliers were thoroughly vetted during bid evaluation to ensure that they were in good standing with Medicare and met Medicare enrollment rules, quality and financial standards, and accreditation and state licensure requirements. CMS also screened and evaluated all bids to ensure that they were bona fide and based on real supplier costs. Only qualified bidders with bona fide bids were offered contracts. The bid evaluation process ensured that there would be more than enough suppliers, including small suppliers, to meet the needs of the beneficiaries living in the competitive bidding areas (CBAs). Approximately 51 percent of the winning suppliers from the Round 1 Rebid are small suppliers, well exceeding the 30 percent goal established by CMS. Ninety-two percent of suppliers that were offered a contract accepted the contract terms.

[4] In addition to the larger programmatic changes described above, MIPPA excluded the Puerto Rico MSA and negative pressure wound therapy (NPWT) devices from the Round 1 Rebid.

[5] Round 1 Rebid product categories are: Oxygen Supplies and Equipment; Standard Power Wheelchairs, Scooters, and Related Accessories; Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2); Mail-Order Diabetic Supplies; Enteral Nutrients, Equipment, and Supplies; Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), and Related Supplies and Accessories; Hospital Beds and Related Accessories; Walkers and Related Accessories; and Support Surfaces (Group 2 mattresses and overlays) in Miami only.

While only nine MSAs currently participate in competitive bidding, the program is already generating significant savings for the Federal government and the approximately 2.3 million Medicare fee-for-service beneficiaries residing in the areas where competitive bidding is in effect. According to CMS's analysis of claims from 2010 and 2011,[6] the competitive bidding program has reduced DMEPOS spending by approximately $202.1 million—or 42 percent overall—in the nine Round 1 Rebid areas. The program has significantly reduced payment amounts, with an average price reduction of 35 percent from the fee schedule. For example, if Medicare suppliers in the nine CBAs had instead been paid the 2011 Medicare fee-schedule amounts, Medicare suppliers would have been paid $173.31 per month for stationary oxygen equipment (e.g., oxygen concentrators), of which the beneficiary would have paid 20 percent in cost-sharing. The supplier would have received $2,079.72 over the course of the year, of which the beneficiary would have paid $415.94 in cost-sharing. Under the competitive bidding program, the average Medicare allowed monthly payment amount for stationary oxygen equipment in the nine competitive bidding areas has been reduced by 33 percent from $173.31 to $116.16. Further, a beneficiary's cost-sharing responsibility for stationary oxygen equipment rental for a year has been reduced by an average of $137 in the nine areas.

The Round 1 Rebid contract period for all product categories except mail-order diabetic supplies expires on Dec 31, 2013. CMS is required by law to recompete contracts under the DMEPOS Competitive Bidding Program at least once every three years. Earlier this year, CMS announced plans to recompete the supplier contracts awarded in the Round 1 Rebid and conducted a pre-bidding awareness program to encourage suppliers to prepare for bidding. On August 16, 2012, CMS announced the bidding schedule for the Round 1 Recompete and started a comprehensive bidder education program. Bidder registration began on August 20, 2012, and the 60-day bid window is scheduled to open on October 15, 2012.

[6] Medicare fee-for-service claims. Savings derived by comparing 2010 to 2011 Part B-allowed charges, which include program expenditures and beneficiary cost-sharing. Claims for 2011 are estimated to be 98 percent complete.

Monitoring of Beneficiary Health Status and Access

CMS has closely monitored the results of the competitive bidding program since implementation to ensure that savings goals of the program have been achieved and – more importantly – to ensure that beneficiary access to appropriate supplies and equipment has not been compromised. To ensure effective monitoring, CMS implemented a real-time claims monitoring system which analyzes the utilization of the nine product categories. CMS' claims monitoring system was designed to pay particular attention to potential changes in key secondary indicators such as hospital admissions, emergency room visits, physician visits, and admissions to skilled nursing facilities before and after the implementation of the new payment model. To conduct this monitoring, the system looks at three comparison groups of beneficiaries over time: 1) all Medicare beneficiaries living in one of the nine areas compared to beneficiaries living in a similar geographic area not yet subject to competitive bidding (*e.g.*, Orlando vs. Tampa); 2) beneficiaries most likely to use a particular item living in one of the nine areas compared to beneficiaries most likely to use the item in a similar geographic area; and 3) beneficiaries actually using an item living in one of the nine areas compared to beneficiaries actually using an item living in a similar geographic area. Beneficiaries are considered likely to use a competitively bid item based on the presence of particular health conditions (for instance, patients with pulmonary disease are monitored for use of oxygen therapy).

For the first year of the program, CMS' real-time claims monitoring and subsequent follow-up has indicated that beneficiary access to all necessary and appropriate items and supplies has been preserved in the nine CBAs. Moreover, utilization of hospital services, emergency room visits, physician visits, and skilled nursing facility care has remained consistent with the patterns and trends seen throughout the rest of the country. The results of our claims monitoring are regularly posted on the CMS website.[7]

Using the information generated by the real time monitoring, CMS has conducted follow up as necessary. For example, CMS' monitoring revealed declines in the use of mail-order diabetes test strips and Continuous Positive Airway Pressure (CPAP) supplies in the CBAs. In response

[7] Health status monitoring summaries are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html.

to these utilization declines, CMS initiated three rounds of outbound phone calls to users of these supplies in the nine CBAs, two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011. The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, which would suggest that beneficiaries had historically received excessive replacement supplies before they were medically necessary. As a result of this monitoring, CMS concludes that the competitive bidding program may have curbed previous inappropriate distribution of these supplies.

In addition to careful monitoring of beneficiary health status, CMS is tracking the number of inquiries and complaints made to our regional offices, 1-800-MEDICARE, and the Medicare Competitive Acquisition Ombudsman's Office. During pre-implementation education, CMS aggressively marketed the 1-800-MEDICARE call center as a primary information tool for beneficiaries. In 2011, CMS received 127,466 beneficiary inquiries regarding the competitive bidding program, which represented less than 1 percent of total call volume at the 1-800-MEDICARE call center. The vast majority of inquiries were about routine matters such as questions about the program or finding a contract supplier. The number of overall beneficiary complaints, defined as inquiries that express dissatisfaction with the program and cannot be resolved by a call center operator, continues to be minimal. All complaints were assigned to program experts for prompt resolution. In the fourth quarter of 2011, CMS received complaints from only six beneficiaries. This is a minute fraction of the 2.3 million fee-for-service beneficiaries residing in the nine CBAs.

Table 1: Beneficiary Complaints by Quarter, 2011

	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Beneficiary Complaints	43	73	29	6	151

The small number of beneficiary inquiries and complaints further corroborate the positive results shown in the real-time claims monitoring data.

Round 2 Expansion and National Mail Order Competition

Building on the success of the Round 1 Rebid, CMS is expanding the competitive bidding program to 91 additional areas as required by MIPPA and the Affordable Care Act. The bidding process is very similar to the process used successfully in the Round 1 Rebid, with minor adjustments. In addition to the items included in the Round 1 Rebid, CMS has expanded the list of items bid by combining standard manual wheelchairs, standard power wheelchairs, and scooters to form a new expanded standard mobility device product category; expanding bidding for support surfaces throughout all Round 2 areas; and adding negative pressure wound therapy pumps and related supplies and accessories as an additional product category. CMS is also conducting a national mail-order competition for diabetic testing supplies at the same time as Round 2. The national mail-order competition includes all 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. The bidding window was open from January 30 to March 30, 2012. CMS is currently evaluating the bids received and expects to announce the payment amounts and begin the contracting process in Fall 2012, with an announcement of contract suppliers in Spring 2013. We anticipate that the Round 2 and national mail-order program contracts and prices will be implemented in July 2013.

CMS is continuing to make additional improvements in the bidding process for Round 2, focusing on increasing the scrutiny of bids and enhancing the successful bidder education program. CMS already used a rigorous bona fide bid review process in Round 1 to protect against unrealistic low bids. During the Round 1 Rebid bid evaluation, we found that about 8 percent of bids were extremely low in comparison to other bids, so we asked these bidders to send us invoices and rationales explaining how they could furnish items at the bid price. Bidders were able to prove that 67 percent of these comparatively low bids were feasible. We rejected all of the bids that were not proven feasible, and we did not offer contracts to these suppliers or include the rejected bids in the calculation of single payment amounts. CMS is strengthening this rigorous process for Round 2 by focusing more on the highest costs, highest volume items and subjecting more bids to additional review beyond the initial screening and evaluation process. CMS also improved bidder education materials to emphasize more strongly the need to submit bids that include the cost for the supplier to buy the item, overhead, and profit.

To help the large number of suppliers in these MSAs understand the process, CMS launched a bidder education program in November 2011. This program was designed to ensure that all DMEPOS suppliers, including small suppliers, interested in bidding received the information and assistance they needed to submit complete bids in a timely manner. Comprehensive information on an array of topics, including bidding rules, user guides, policy fact sheets, checklists and bidding information charts, was made available at http://www.dmecompetitivebid.com. The educational materials explained the small supplier protections provided by the program. Bidders could also call a toll free help desk with expanded hours with any questions about the bidding process. The bidder education program featured numerous enhancements such as improved Request for Bids instructions, updated fact sheets, and a series of educational webcasts. The webcasts were posted online and could be accessed 24 hours a day to ensure maximum opportunities for suppliers to review them.

CMS recognizes that the success of Round 2 will require significant efforts to educate beneficiaries, beneficiary partners, providers, stakeholders and contract suppliers about the program and, accordingly, is preparing to scale up the successful education and outreach efforts used in Round 1. The primary goal of this education campaign will be to keep beneficiaries, caregivers, referral agents (e.g., hospital discharge planners and physicians), and other stakeholders informed about the program and how it affects them. Outreach to beneficiaries will include fact sheets, brochures and booklets, Frequently Asked Questions and other postings on medicare.gov, newsletters, an update to the annual *Medicare & You Handbook*, emails, and letters. In addition, our 1-800-MEDICARE customer service representatives and direct service caseworkers are being trained and educated so they are better able to assist beneficiaries who may come to them with questions about the program.

CMS will deploy our central and regional office staff, along with local ombudsmen to work with providers of health care services, established networks of providers, and beneficiary advocacy organization partners to keep beneficiaries informed. Outreach to physicians, social workers, referral agents, discharge planners and others will be delivered through the various listservs, and through the Medicare Learning Network (MLN), via MLN Matters articles, fact sheets, brochures, and national provider calls. Educational materials for medical professionals will be available on the cms.gov website and are also communicated through national and State/local

provider associations covering all provider types, as well as through the Medicare fee-for-service contractors via their websites, listservs, bulletins and educational seminars. CMS plans to begin Round 2 outreach activities in the coming months, working first to make beneficiaries and stakeholders aware of the program and its benefits, while allaying potential concerns or confusion.

Conclusion

The DMEPOS competitive bidding program is saving money for Medicare and beneficiaries, while continuing to provide access to high quality supplies to those who need them. Over a year into the program, CMS has demonstrated that the program has had no negative impacts to the health of our beneficiaries and has curbed inappropriate use of certain items. As we seek ways to strengthen and preserve Medicare, DMEPOS competitive bidding serves as part of the solution, generating significant long-term savings to the Medicare Part B Trust Fund.

CMS looks forward to building on this success with the implementation of Round 2 of the program and will strive for continual improvement as it expands to serve more beneficiaries. Throughout the implementation process, CMS has appreciated the interest and feedback of Members of this Subcommittee and your constituents as we strive to make the program as effective as possible for the suppliers and beneficiaries in your districts. We look forward to continuing to work with you on this important initiative.