



**STATEMENT OF**

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**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**ON**

**THE IMPACT OF COMPETITIVE BIDDING ON SMALL**  
**BUSINESSES IN THE DURABLE MEDICAL EQUIPMENT COMMUNITY**

**BEFORE THE**

**HOUSE COMMITTEE ON SMALL BUSINESS**  
**SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP**

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**Testimony of**

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**Before the  
House Committee on Small Business  
Subcommittee on Rural and Urban Entrepreneurship  
On**

***The Impact of Competitive Bidding on Small  
Businesses in the Durable Medical Equipment Community***

**February 11, 2009**

Good morning Chairman Shuler, Ranking Member Leutkemeyer, 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 durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program created by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and temporarily delayed by the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. This program was enacted by Congress to provide greater value to the Medicare program, beneficiaries and taxpayers. When fully implemented, this initiative is expected to reduce beneficiary out-of-pocket costs and ensure their access to high quality DMEPOS items and services, bring Medicare's DMEPOS payments in line with current market pricing, and combat supplier fraud, which is expected to result in taxpayer savings of billions of dollars.

**Overview**

CMS is the largest purchaser of health care in the United States, serving over 92 million Medicare, Medicaid, and SCHIP beneficiaries. Medicare alone covers roughly 44 million individuals, with total gross Medicare benefit outlays and administrative costs projected

to reach approximately \$499 billion in Fiscal Year 2009.<sup>1</sup> CMS projects that gross spending for Medicare will equal approximately \$8.7 billion on DME alone in 2009.<sup>2</sup> Each year, DMEPOS suppliers provide items and services including power wheelchairs, oxygen equipment, walkers and hospital beds to millions of Medicare beneficiaries.

Medicare payment for DMEPOS items and services is generally based on fee schedule amounts for covered items. In general, fee schedule amounts are calculated using historical supplier charge data from about 20 years ago that may not be reflective of an appropriate payment amount for today's market. Relying on historical charge data has resulted in Medicare payment rates that are often higher than prices charged for identical items and services when furnished to non-Medicare customers. Medicare beneficiaries and taxpayers bear some of the cost of these inflated charges. Table 1 shows the differences between current Medicare payment amounts for certain DMEPOS items compared to the average prices a consumer would see if shopping for that device on the Internet.

**Table 1: Illustrative Comparison Prices Pre-Competitive Bidding**

<i>DMEPOS Items (rank by use)</i>	<i>CMS payment based on fee schedule amount (% of average internet price)</i>	<i>Illustrative Average Internet Pricing</i>	<i>CMS payment above average internet price</i>
Oxygen concentrator (#1)	\$2,380 (+352%)	\$677	\$1,703
Standard power mobility device (#3)	\$4,023 (+185%)	\$2,174	\$1,849
Hospital bed (#4)	\$1,825 (+242%)	\$754	\$1,071
Continuous positive airway pressure device (#5)	\$1,452 (+517%)	\$281	\$1,171
Respiratory assist device BIPAP (Bi-level Positive Airway Pressure) (#18)	\$3,335 (+247%)	\$1,348	\$1,987

<sup>1</sup> Department of Health and Human Services, Budget in Brief: Fiscal Year 2009.

<sup>2</sup> CMS Office of the Actuary, 2009 Mid-session Review.

The DMEPOS competitive bidding will result in beneficiary savings as a result of lower coinsurance for these products. Competitive bidding will also reduce the amount Medicare pays for these items and will bring these amounts in line with current market prices. Before the MIPPA delay, we estimated that by 2010 the program was projected to save Medicare and taxpayers \$1 billion annually<sup>3</sup> – and these savings will directly translate to lower coinsurance for beneficiaries. After 2010, savings would have increased in subsequent rounds of the program, as additional DMEPOS items and services became subject to competitive bidding. The competitive bidding statute also requires CMS to include additional areas in subsequent rounds of the program. Further, the projected overall savings to Part B of the Medicare program should slow the annual increase of the Part B premium Medicare beneficiaries pay each month.

In 2008, after only two weeks of implementation, Congress enacted MIPPA which imposed a temporary delay to the competitive bidding program and included other limited changes. The law required CMS to terminate the existing contracts that were awarded in Round 1 and conduct a second Round 1 competition (the “Round 1 rebid”) in 2009. Additionally, the new law established a special document review process and a requirement for contracted suppliers to report to CMS information regarding relationships with suppliers with whom they subcontract. MIPPA also excluded certain DMEPOS items and areas from competitive bidding and provided an exemption to the program for hospitals, physicians, and other treating practitioners that furnish certain types of DMEPOS items to their own patients. CMS plans to issue additional information about the program in the upcoming months, including a complete timetable of the Round 1 rebid process.

MIPPA also extended the duration of the Program Advisory and Oversight Committee (PAOC), which advises the Secretary on a number of issues related to the implementation of the program and will help the Secretary focus on key operational issues. CMS has announced new PAOC members with expertise in a broad range of issues, including quality standards, accreditation, and beneficiary issues. The committee includes

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<sup>3</sup> See 72 Fed. Reg. 18079 (April 10, 2007)

representatives of beneficiaries and consumers, physicians and other practitioners, suppliers, states, organizations that are knowledgeable of professional and financial standards, and representatives from industry associations.

On January 16, 2009, CMS issued an interim final rule with comment period (CMS-1561-IFC) to implement certain provisions of section 154 of MIPPA related to the DMEPOS competitive bidding program. Specifically, this rule implements certain provisions that delay implementation of Round 1 of the competitive bidding program; requires CMS to conduct a second Round 1 competition (the "Round 1 rebid") in 2009; and mandates certain changes for both Round 1 rebid and subsequent rounds of the program, including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose CMS information regarding subcontracting relationships. On February 10, 2009, CMS issued a notice (at 74 FR 6557) seeking comment on a contemplated delay of 60 days in the effective date of the interim final rule. CMS is considering a temporary 60-day delay in effective date to allow CMS and U.S. Department of Health and Human Services (HHS) officials the opportunity for further review of the issues raised by this rule, consistent with the memorandum of January 20, 2009, from the Assistant to the President and Chief of Staff, entitled "Regulatory Review," in order for the new Administration to examine this rule carefully to ensure that any concerns are appropriately addressed. In addition, CMS appreciates the opportunity to hear the Committee's concerns.

When combined with Medicare's accreditation, licensure and quality standards efforts, the competitive bidding program will help to assure that high quality service and items continue to be available to beneficiaries who need medical equipment to use at home. The program will also assist CMS in addressing fraud and abuse issues in the current DMEPOS non-competitive system cited by the HHS Office of Inspector General and the U.S. Government Accountability Office.

## Background

Under MMA, competitive bidding programs were to be phased into the Medicare program, with competition under the program beginning in 2007. CMS conducted competition for Round 1 of the program in 10 Metropolitan Statistical Areas (MSAs) and 10 product categories of DMEPOS and successfully implemented the program on July 1, 2008. As determined under the competitive bidding program, the fee schedule amounts are replaced with single payment amounts which are calculated based on bids submitted by suppliers. Medicare's single payment amounts resulted in a projected savings of approximately 26 percent compared to the traditional Medicare fee schedule. This provided substantial savings for Medicare beneficiaries and taxpayers.

These savings directly translated to lower out-of-pocket cost for Medicare beneficiaries. For example, beneficiaries in Orlando who use oxygen would have saved 32 percent. The Medicare fee schedule amounts result in a payment of \$199.28 a month for oxygen rental in Orlando, however, with competitively set payment amounts, the price would have been reduced to \$140.82 per month. The beneficiary, who had been paying coinsurance of \$39.86 per month, would have paid \$28.17 per month under this program, a savings of \$140 per year. In Charlotte and Cincinnati, beneficiaries would have saved 30 percent, Miami beneficiaries would have saved 29 percent, Pittsburgh 28 percent, Cleveland 27 percent, Kansas City 25 percent, Dallas 23 percent and Riverside 22 percent.<sup>4</sup>

Average savings generated for some commonly used items, for which Medicare pays 80 percent and beneficiaries pay 20 percent of the allowed amount following payment of the annual Part B deductible, is summarized in the following chart:<sup>5</sup>

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<sup>4</sup> CMS data derived from bid results  
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<http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2993&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date>

### Examples of Medicare and Beneficiary Savings Based on the Previous Round 1

Item/Period of Service	2008 Fee Schedule Payment Amount**	New Single Payment Amount Under Competitive Bidding** <sup>6</sup>	Medicare Savings 80% of Difference	Beneficiary Savings 20% of Difference
<b>Concentrator</b>				
Per month	\$199.28	\$140.82	\$46.77	\$11.69
Per year	\$2,391.36	\$1,689.84	\$561.24	\$140.28
Per 3 years*	\$7,174.08	\$5,069.52	\$1,683.72	\$420.84
<b>Hospital Bed</b>				
Per month	\$140.46	\$99.28	\$32.94	\$8.24
Per 13 months*	\$1,474.78	\$1,042.46	\$345.86	\$86.46
<b>Diabetic Supplies</b>				
Per month	\$82.68	\$47.53	\$28.12	\$7.03
Per year	\$992.16	\$570.36	\$337.44	\$84.36
Per 3 years	\$2,976.48	\$1,711.08	\$1,012.32	\$253.08

\* Suppliers retain ownership of oxygen equipment after end of rental payment period of 36 months. Suppliers must transfer title of capped rental items (e.g. hospital beds) after the end of the rental payment period of 13 months.

\*\* 20% of current and new allowed amount is paid by the beneficiary out-of-pocket using 2008 allowed amounts

For example, under the competitive bidding program, the average Medicare-allowed monthly payment amount for diabetic supplies in the competitive bidding areas would have been reduced by 43 percent from \$82.68 to \$47.53, in those cases where the beneficiary chose to obtain the supplies on a mail order basis. If the beneficiary did not wish to receive their replacement testing supplies in the mail, they could have elected to obtain them from a local store with no reduction in the fee schedule amount or beneficiary coinsurance amount.

MIPPA requires competition for the Round 1 rebid to occur in 2009 and in the same areas included in the previous first round except for San Juan, Puerto Rico. In 2010, Medicare payment to suppliers for competitively bid DMEPOS items and services will be at the single payment amount. As with the previous first round of competitive bidding,

<sup>6</sup> Average of the single payment amounts for the various competitive bidding areas.

suppliers who meet all of the requirements of the program and submit bids in the winning range will be awarded contracts in designated competitive bidding areas. These Round 1 Medicare contract suppliers will then furnish competitively bid items and services to beneficiaries in the 9 competitive bid areas and will be monitored by CMS on their performance, quality and customer service. Requiring suppliers to submit bids, including information on accreditation and financial standards, will ensure continued access to high-quality medical equipment and supplies at more reasonable prices to beneficiaries and the Medicare program. These changes, which will result in pricing more consistent with those offered to non-Medicare payers and improved oversight, also support CMS' efforts to reduce Medicare waste, fraud and abuse.

### **Quality and Financial Standards**

The program provides important safeguards to ensure high quality, good customer service, and improved oversight prevention against fraud. These safeguards also ensure a level playing field for suppliers competing for contracts under the competitive bidding program.

*Quality and Accreditation Standards.* The MMA required the Secretary to establish quality standards for DMEPOS suppliers to be applied by independent accreditation organizations. MIPPA extended this requirement so that suppliers furnishing items and services as subcontractors under the competitive bidding program must also meet the same accreditation requirements as contract suppliers. The DMEPOS quality standards address the set up and delivery of items and services, beneficiary education on the use of these products, suppliers' accountability, business integrity, performance management, and other areas. CMS conducted a wide variety of activities to involve stakeholders (including many targeted specifically for small business suppliers) and the public in development of these standards, including conducting focus groups and open door forums, consulting with industry stakeholders, and publicizing the draft standards.

CMS received more than 5,600 public comments on the draft quality standards. Based on these comments, we made significant revisions to reduce the burden on small suppliers

while continuing to ensure quality services for Medicare beneficiaries. All suppliers selected as Medicare contract suppliers in Round 1 of the competitive bidding program must have been accredited under these standards, and all DMEPOS suppliers nationally must be accredited by September 30, 2009, subject to an exception for “eligible professionals” passed by Congress last year.

*Financially viable business partners.* The MMA also required that suppliers meet financial standards established by the Secretary in order to contract with Medicare under the competitive bidding program. These financial standards as outlined in the Request for Bids allow Medicare to assess the ability of suppliers to provide quality items and services in sufficient quantities to meet beneficiaries’ needs. Ultimately, financial standards for suppliers will help maintain beneficiary access to quality items and services by ensuring that contract suppliers are viable entities able to consistently provide quality items and services to patients for the life of their contracts. They also help to weed out disreputable businesses that prey on Medicare and beneficiaries. As part of bid solicitation, each supplier submitted required financial documentation, including balance sheets, statements of cash flow, and profit and loss statements from tax returns. CMS evaluated each bidder’s financial documentation to determine whether the supplier had met the standards required to participate in the program.

It is important to note that the financial documentation requirements were developed in a way that considers small suppliers’ business practices and constraints, while remaining consistent with the financial standards mandate of the MMA. During the previous Round 1 bidding process, we limited the number of financial documents that a supplier was required to submit so that the requirement would be less burdensome for all suppliers, including small suppliers. For the Round 1 rebid, we will further reduce the burden on suppliers by requiring financial documents for only 1 year rather than 3 years.<sup>7</sup> We believe we have balanced the needs of small suppliers with the needs of beneficiaries in requesting documents that will provide us with sufficient information to determine the financial soundness of a supplier, regardless of its size.

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<sup>7</sup> See 74 Fed. Reg. 2873, 2876 (January 16, 2009).

During the previous Round 1, a number of suppliers had their bids disqualified, and the majority of these were for failing to submit the supporting financial documentation that was outlined in the Request for Bids. This documentation is critical for determining whether suppliers meet financial standards, as required by the MMA. These standards are essential to ensure that Medicare contracts only with financially sound suppliers capable of serving beneficiaries' needs over the life of the contract.

For the Round 1 rebid, pursuant to MIPPA, we will implement a special document review process. Under this process, CMS will notify suppliers that submit financial documents within specified timeframes of each financial document that is missing from the bidder's submission as of that timeframe.

### **Implementing Regulations**

Two underlying goals of the competitive bidding program are ensuring that beneficiaries maintain access to quality items and services and that small suppliers have an opportunity to participate in the program.

*Beneficiary protections.* We anticipate that competitive bidding will save money for beneficiaries and taxpayers, while ensuring beneficiary access to quality items and services. The following are specific examples of the beneficiary protections established in the competitive bidding program:

- Contract suppliers must be accredited and meet applicable licensure requirements and established financial and quality standards. Subcontractors that furnish services under the competitive bidding program must also be identified, meet applicable quality standards and licensure requirements, and be accredited. As a result, we will maintain a business model that supports quality, customer service, and access to care for beneficiaries. The independent accrediting organizations will play a key role in ensuring that contract suppliers meet these quality standards.

- CMS' regulations require that multiple contract suppliers are selected to meet beneficiary demand in each competitive bidding area. This means that beneficiaries will have access to the services they need and that competition among winning suppliers, based on quality and customer service, will provide beneficiaries with choices regarding the source of their medical equipment and supplies.
- When a physician specifically prescribes a particular brand name product or mode of delivery to avoid an adverse medical outcome, contract suppliers are required either to furnish that item or mode of delivery, to assist the beneficiary in finding another contract supplier in the competitive bidding area that can provide that item or service, or to consult with the physician to find a suitable alternative product or mode of delivery for the beneficiary.
- Beneficiaries will be able to obtain repairs of equipment they own from either a contract or non-contract supplier with a valid Medicare billing number.
- Replacement parts needed to repair beneficiary-owned equipment may also be obtained by a beneficiary from either a contract or non-contract supplier with a valid Medicare billing number, even if the parts are competitively bid items.
- Contract suppliers are required to make available to beneficiaries in competitive bidding areas the same items and services that they make available to other Medicare and non-Medicare customers. For transparency, we will post on our Web site a list of brands furnished by each contract supplier.

*Small Supplier Considerations.* While developing this important new 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 pay close attention to the concerns of these constituencies, in particular those of small suppliers.

During the implementation of the previous Round 1 of competitive bidding, CMS adopted numerous strategies to ensure small suppliers have the opportunity to be considered for participation in the program. For example:

- CMS worked in coordination with the Small Business Administration (SBA) to develop an 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 SBA’s previous standard of \$6.5 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 also 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 in the number of contracts awarded by CMS beyond the statutory threshold of two contracts per product category per CBA.

- The regulation also established a 30 percent target for small supplier participation in the program. The results of the contracting process for the previous Round 1 were that 64 percent of all contract suppliers were small suppliers.

Physician-Patient Relationship. CMS recognizes that under existing Medicare law and policies, physicians and other treating practitioners sometimes supply certain items of DMEPOS to their patients as part of their professional service. The competitive bidding program preserves this physician-patient relationship by allowing physicians and other treating practitioners to continue supplying certain items to their patients without participating in the bidding process. MIPPA expanded this exemption to include hospitals furnishing these DMEPOS items and services to their patients during an admission or on the date of discharge.

Considerations for Low Population Density Areas and Rural Areas. The statute, as amended by MIPPA, mandates that after Round 2 and before 2015, the following are exempt from competition:

- Rural areas,
- Metropolitan statistical areas not selected under Round 1 or Round 2 with a population of less than 250,000, and
- Areas with a low population density within a metropolitan statistical area that is otherwise selected.

The program as set forth by the MMA provides CMS with discretionary authority for exempting low population density areas within urban areas and rural areas that “are not competitive” from competitive bidding unless there is a significant national market through mail order for a particular item or service. We used this discretionary authority in the previous Round 1 to exempt a large portion of Eastern Riverside and San Bernardino Counties in the Riverside MSA. We also exempted whole counties in the Dallas, Cincinnati, and Kansas City MSAs. We determined that these areas had population densities that were too low relative to other parts of the MSA and that the allowed charges for DMEPOS items attributed to these areas were low relative to the

MSA as a whole, indicating that the areas were not competitive when compared to other parts of the MSA. We will use a similar process to determine which areas will be exempted during Round Two.

### **Outreach**

Before launching the program in July 2008, CMS conducted a comprehensive education and outreach campaign to beneficiaries, caregivers, providers, partner groups, referral agents and suppliers to ensure that beneficiaries, providers, and suppliers in the Medicare program had the information and resources to understand the DMEPOS competitive bidding program and that suppliers had sufficient information to submit bids for participation in the program. This outreach campaign made use of direct mailings, fact sheets, partner group conversations, bidder conferences, open door forums, informational websites, and listserv emails at both the regional and national levels. CMS will continue to extensively educate stakeholders to the competitive bidding program when the program begins again in 2009.

### **Conclusion**

The previous round of the competitive bidding program has shown that the program can provide value to both patients and Medicare, while ensuring delivery of quality items and services. Medicare beneficiaries in CBAs would have realized, on average, a 26 percent savings on certain commonly used DMEPOS, and small suppliers accounted for 64 percent of the winning bids. The application of quality and financial standards means that beneficiaries will receive superior customer service from legitimate suppliers. CMS looks forward to the re-implementation of the program with the improvements mandated by MIPPA, and a number of other clarifications now under development by CMS. CMS has taken care to design and implement this program in a way that emphasizes the needs of beneficiaries while addressing the concerns of small suppliers. In the coming months, CMS will provide more information to suppliers and beneficiaries regarding the details of the program and timeline for implementation, consistent with the law.