HEARING ON THE MEDICARE DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

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CONTENTS

HEARING ON THE MEDICARE DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM

WEDNESDAY, MAY 9, 2012

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
Washington, DC.

The subcommittee met, pursuant to call, at 9:03 a.m., in Room 1100, Longworth House Office Building, Honorable Wally Herger [chairman of the subcommittee] presiding.

[The advisory of the hearing follows:]

HEARING ADVISORY

Chairman Herger Announces Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program

Wednesday, May 09, 2012

House Ways and Means Health Subcommittee Chairman Wally Herger (R–CA) today announced that the Subcommittee on Health will hold a hearing to examine the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program to understand how the program is impacting patients, suppliers, and program expenditures. This hearing will help the Subcommittee assess the Round 1 experience in nine Metropolitan Statistical Areas (MSAs) and the plans for its 2013 expansion into 91 additional MSAs. **The hearing will take place on Wednesday, May 9, 2012, in 1100 Longworth House Office Building, beginning at 9:00 A.M.**

In view of the limited time available to hear from witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing. A list of witnesses will follow.

BACKGROUND:

The Medicare Modernization Act of 2003 (MMA) established the DMEPOS competitive bidding program to bring Medicare payments for certain high-cost and high-volume items—such as hospital beds and diabetic testing supplies—in line with actual market prices, as Medicare reimbursement rates often far exceeded retail rates. The Centers for Medicare and Medicaid Services (CMS) competitive bidding process entails DMEPOS suppliers submitting bids that include the price at which they are willing to sell a specific item in an MSA and the percentage of the market they would serve at that price. Contracts have been offered to the lowest bidders with sufficient capacity to serve the market.

MMA specified that Round 1 of the competitive bidding program was to begin in 10 MSAs in 2007. In response to concerns that the CMS handling of the process for awarding contracts to suppliers had significant flaws, Congress terminated Round 1 two weeks after the program began with passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition to making improvements to the program, MIPPA mandated that a modified version of Round 1 be re-bid and implemented in 2011, and that the number of MSAs be reduced to nine. The cost of this delay was offset by a 9.5 percent reduction in 2009 DMEPOS fee schedule payments for competitively bid items. Recently, the Medicare actuaries found that Round 1 has reduced program expenditures by $202 million in 2011.

The competitive bidding program will soon undergo significant expansion beyond the initial nine MSAs. The Affordable Care Act (ACA) expanded the program so that Round 2 includes an additional 91 MSAs. CMS is now assessing supplier bids for Round 2 with the intent that competitively bid prices in these 91 MSAs take effect in mid-2013. The ACA directed the Secretary of the Department of Health and Human Services to use competitively bid prices nationwide beginning in 2016. The Medicare actuaries expect the competitive bidding program to save $43 billion over the next 10 years, including saving beneficiaries $17 billion, relative to the prior fee schedule-based system.

In announcing the hearing, Chairman Herger stated, **"Congress established the competitive bidding program in light of evidence that the Medicare fee schedule payments far exceeded retail rates, leaving the DMEPOS benefit prone to waste, fraud, and abuse. I believe strongly in the competitive forces of the private market and the first year of the program shows this**

process has resulted in lower costs for Medicare and its beneficiaries. While this is encouraging, it is important to ensure the process by which suppliers compete is fair and that beneficiaries receive needed care. This hearing will help the Subcommittee understand the successes and challenges with Round 1 before the program's scheduled significant expansion next year."

FOCUS OF THE HEARING:

The hearing will focus on the impact of the DMEPOS competitive bidding program on beneficiaries, suppliers, and Medicare expenditures and the implications for program expansion.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "Hearings." Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Wednesday, May 23, 2012**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721 or (202) 225–3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone, and fax numbers of each witness.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://www.waysandmeans.house.gov/*.

Chairman HERGER. The subcommittee will come to order. We are here today to assess the impact of the Medicare Durable Med-

ical Equipment Competitive Bidding Program. Our intent is to understand the program's impact on beneficiaries, suppliers, and Medicare expenditures, and the implications or program expansion. Congress mandated the use of competitive bidding to establish payment rates for high cost and high volume DME and Medicare Modernization Act of 2003. Congress took this action in response to evidence that Medicare fee schedule payment rates often far exceed retail prices.

In fact, in some cases, Medicare beneficiary copays exceeded the cost of the device on the open market. These generous payment rates also made the DME benefit especially vulnerable to waste, fraud, and abuse. A successful small-scale test required through the Balanced Budget Act of 1997 showed that competitive bidding for DME was feasible. Consistent with the statutes the Centers for Medicare and Medicaid Services implemented a competitive bidding process for nine DME product categories in nine geographic areas on January 1st, 2011.

This first phase of implementation is known as Round 1. Medicare is in the process of expanding the competitive bidding program to an additional 91 areas with competition-based payment amounts to take effect in mid 2013. This expansion is referred to as Round 2. The DME supplier industry has long had concerns about the use of competitive bidding. It is important to understand these concerns, not only because numerous beneficiaries rely on medical equipment to keep them in their homes and out of the hospital, but also because many suppliers are the kinds of small businesses that form the background of our economy.

Congress, with input from members of this committee, responded to supplier concerns that the initial CMS effort to implement competitive bidding was flawed. As a result, we passed the Medicare Improvements for Patients and Providers Act in 2008, which terminated the initial Round 1 and required that it be a bid once improvements were made. That said, it is important that Medicare pay a reasonable and responsible price for DME so that beneficiary and taxpayer dollars are used wisely.

CMS has reported that the competitive bidding program resulted in $200 million in savings in 2011. These first-year program savings are derived largely from competition-based payment amounts that are on average, 32 percent lower than DME fee schedule prices. And these lower prices mean that beneficiaries are paying less in the form of their 20 percent coinsurance.

A comparison of the Medicare payment for an oxygen concentrator, a common DME item, shows how the Medicare program and its beneficiaries benefit from lower prices derived from the competitive bidding. In the nine Round 1 MSAs, Medicare would have paid $2,080 under the DME fee schedule with a beneficiary paying 20 percent, or $416 on average. By contrast, with competitive bidding, Medicare paid $1,395 and the beneficiary paid $279 on average.

While I strongly believe in the competitive forces of the private market, the process by which the competition is conducted must be fair. To help the subcommittee understand the successes and challenges associated with Round 1, before the program scheduled expansion next year, we will hear from witnesses who collectively

provide a balanced range of perspectives on the competitive bidding program.

Before I recognize Ranking Member Stark, but I understand we will have Congressman Thompson speaking for him, I ask unanimous consent that all members' written statements be included in the record. Without objection, so ordered.

Chairman HERGER. I now recognize the gentleman from California, for 5 minutes.

Mr. THOMPSON. Chairman Herger, thank you for holding this hearing on Medicare's Durable Medical Equipment Competitive Bidding Program. Last year, we held a hearing on this topic in May 2008, and what a different several years can make. That hearing revealed serious problems with the implementation of competitive bidding for DME. The health subcommittee worked together on bipartisan legislation to delay implementation of Round 1. Importantly, we didn't just give the industry a pass. We reduced DME payments nationwide by 9.5 percent for all product categories that would have been in the DME demonstration, and we required CMS to revise the program to avoid missteps from the initial implementation effort.

Historically, this subcommittee has raised concerns with competitive bidding. We want higher quality and lower prices. We can simply implement those changes through the fee schedule and other administrative tools.

I have serious concerns about using competitive bidding for other services, but purchasing equipment is a fairly straightforward transaction, and I have been pleasantly surprised by the outcome of the Round 1 rebid. Unlike the first try, we haven't heard an outcry from suppliers around the country facing difficulties in filling applications.

CMS really seems to have worked diligently to address the operational programs—problems that plagued the inept attempt—initial attempt. Not only does the demonstration appear to have been implemented smoothly, it also appears that many of our concerns about negative beneficiary effects haven't occurred. We typically hear directly from patients or their advocates when there are problems with such a substantial change to Medicare.

I can report that we have not received any beneficiary complaints with regard to this demonstration. However, we need to be cautious as we proceed toward further expansion and remain ever diligent in looking out for negative effects for beneficiaries. I look forward to hearing from both CMS and the GAO today.

In particular, I would like to thank the GAO for working with us to expedite release of their statutorily mandated report on the Round 1 rebid program. GAO's work is the first outside audit of this demonstration and I am especially interested in their expert evaluation.

Our second panel will also be important. We will hear from several DME suppliers and a patient advocate, all of whom will present their opinions on the DME competitive bidding program to date.

We need to be circumspect about drawing significant conclusions from this hearing. We will hear an overview of the program in only nine metropolitan statistical areas across our country. The program

will expand next year to an additional 91 areas. While Round 1 impacts 6 percent of Medicare's beneficiaries, Round 2 will increase that to more than half of all Medicare beneficiaries. That is a substantial increase. While the evidence appears to indicate that CMS can expand this program, while protecting beneficiary access to care, saving money for beneficiaries through lowered cost sharing, and recouping savings for taxpayers through lower overall Medicare spending, continued close scrutiny is necessary. DME is an important benefit. It enables people to remain in the community, and out of institutions.

We have a duty, a duty to Medicare beneficiaries and to America's taxpayers to ensure that we maintain access to quality care at the best price available. With that, I yield back the balance of Mr. Stark's time.

Chairman HERGER. Thank you. On our first panel the subcommittee will hear from two Government agencies. Laurence Wilson, who is the director of the Chronic Care Policy Group and the Center for Medicare at CMS will discuss the agency's efforts to implement the competitive bidding program. Our second Government witness is Kathleen King, who is the Director of Health Care at the Government Accounting Office. Congress mandated that GAO study the competitive bidding program. We look forward to hearing from Ms. King on what her agency has found.

Mr. King, you are now recognized for 5 minutes—excuse me. Mr. Wilson, you are recognized for 5 minutes.

STATEMENT OF LAURENCE WILSON, DIRECTOR, CHRONIC CARE POLICY GROUP, CENTER FOR MEDICARE, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. WILSON. Good morning, Chairman Herger, Mr. Thompson, and ranking members—and distinguished Members of the Subcommittee. I am pleased to be here today to discuss the Durable Medical Equipment Prosthetic Orthotics and Supplies Competitive Bidding Program. This important initiative, required under the Medicare Modernization Act of 2003, and recently expanded under the Affordable Care Act, has been effective in reducing beneficiary out-of-pocket costs, improving the accuracy of Medicare's payments, reducing overutilization and ensuring beneficiary access to high-quality items and services.

CMS successfully implemented the program on January 1, 2011, in nine metropolitan areas after making a number of important improvements based on new requirements from Congress and after listening to feedback from our stakeholders. We are pleased to report that the program has saved $202 million in its first year of operation a reduction of over 42 percent compared to 2010, with no disruption in access, or negative health consequences for beneficiaries. We are now continuing with the expansion of the program to 91 additional areas of the country as the law requires.

CMS worked closely with stakeholders to design and implement the program in a way that is fair for suppliers, and sensitive to the care needs of beneficiaries. For example, the program includes provisions to promote small supplier participation and numerous protections for beneficiaries. The program results in a large number of winners so that beneficiaries are assured access and choice and

there will continue to be competition among contract suppliers on the basis of customer service and quality.

In addition, quality standards and accreditation combined with financial standards provide safeguards to support good quality and customer service, while acting to weed out bad actors and ensure a level playing field for legitimate suppliers. The many improvements made by Congress and CMS have been carried forward to successive rounds of the program. These changes provide for a fair process that is less complex for suppliers to navigate, and result in more effective scrutiny of suppliers' qualifications and the integrity of their bids. We continue to make further improvements as the program expands. For example, to help fulfill our commitment to beneficiaries to ensure quality and good service, our comprehensive monitoring system will be expanded to cover the 91 additional areas and the various new items.

This state-of-the-art system examines 100 percent of Medicare claims and other data in close to real-time and provides important indications on whether access or quality is threatened. It tracks over 3,400 data points including mortality, utilization, hospitalizations, ER visits, and many others to provide us with information about the Medicare beneficiaries and the services they receive.

As I noted before, we have observed no trends in these health status indicators that cause us concern. Where we have seen more significant reductions in utilization, we have followed through with further investigation. For example, for mail-order diabetic testing supplies, we surveyed beneficiaries and found that they were still testing, but not ordering new strips because they had stockpiles at home, up to a 10-month supply or more, which is an indication of the overutilization occurring prior to when the program took effect.

Our experience with Round 1 has shown that the competitive bidding brings value to Medicare beneficiaries and taxpayers compared to the current fee schedule system. In fact, the average price discount across the nine metropolitan areas, is 35 percent. The CMS actuary projects that the program will save $25.7 billion for Medicare over the next 10 years and another $17.1 billion for beneficiaries through lower coinsurance and premiums. In Orlando, the purchase amount of a standard wheelchair dropped by $1,362. That is a savings of $1,089 for Medicare, and the taxpayers, and an additional $272 in savings for beneficiaries.

We are very pleased with the success of Round 1 of the program. Nevertheless, we recognize that the scope of the program is expanding and that it is a significant change for suppliers and patients. We will continue to monitor implementation closely, and be prepared to act swiftly to address any concerns that may arise on behalf of beneficiaries and suppliers.

We have a network in place, built around our National ombudsman, local ombudsman, regional offices, CMS caseworkers, contractors, and Medicare call centers to address and track questions and concerns.

In summary, we will be diligent and thoughtful in our implementation of this important program as it expands to more areas of the country, and we will continue to be open to further improvements suggested by our stakeholders, Members of Congress, and others.

Again, I very much appreciate the invitation to testify before you today, and would be happy to take any questions.

Chairman HERGER. Thank you.

[The prepared statement of Mr. Wilson follows:]

TESTIMONY IS EMBARGOED UNTIL 9:00 AM WEDNESDAY MAY 9, 2012

STATEMENT OF

LAURENCE D. WILSON

DIRECTOR

CHRONIC CARE POLICY GROUP

CENTER FOR MEDICARE

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

MEDICARE DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM

BEFORE THE

U.S. HOUSE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

MAY 9, 2012

Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
U.S. House Committee on Ways and Means, Subcommittee on Health
May 9, 2012

Chairman Herger, Ranking Member Stark, 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.

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.

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. 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)[1], 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 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

[1] 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.

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 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. 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.

Round 1 Rebid

With these improvements 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.[2,3] 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

[2] 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.

[3] 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.

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 business 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 business suppliers, well exceeding the 30 percent goal established by CMS. Ninety-two percent of suppliers that were offered a contract accepted the contract terms.

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,[4] 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.

[4] 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.[5]

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 to these utilization declines, CMS initiated three rounds of outbound phone calls to users of these

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

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 already in the process of 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 DMEPOS 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. 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.

Chairman HERGER. Ms. King, you are now recognized for 5 minutes.

STATEMENT OF KATHLEEN KING, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

Ms. KING. Chairman Herger, and Members of the subcommittee, I am pleased to be here today.

Chairman HERGER. Let's have you push the button.

There is a button in front, I believe.

Mr. RYAN. You have to turn it on.

Ms. KING. It says talk.

Mr. RYAN. Is there a green light that is on in front of you there?

Ms. KING. Is that better?

Chairman HERGER. That is much better.

Ms. KING. I pressed the wrong talk. Chairman Herger, and Members of the Subcommittee, I am pleased to be here today to discuss a report that we are releasing on the Round 1 rebid of the Medicare Competitive Bidding Program for Durable Medical Equipment. Congress directed us to examine several issues regarding the Round 1 rebid, and those are the subject of our report today. We found that the number of bidding suppliers and the number of contracts awarded in the Round 1 rebid were very similar to Round 1. About a third of the 1,011 suppliers, or 356 suppliers that bid in the Round 1 bidding, were awarded at least one contract. CMS made improvements to the bidding process for the Round 1 rebid, and many fewer bids were disqualified in the Round 1 rebid than in Round 1.

However, many suppliers still had difficulty meeting the bid requirements. And, as in Round 1, CMS determined that some suppliers bids had been disqualified incorrectly. Subsequently, CMS extended contracts to seven of those suppliers.

During the first year, few contract suppliers, about 6 percent of those awarded contracts, had their contracts terminated by CMS, voluntarily canceled their contracts, or were involved in ownership changes. Under the program, many noncontract suppliers exercised the option to grandfather rental DME items for beneficiaries they were furnishing those services to prior to the program.

We found that the number of these grandfathered suppliers generally decreased steadily throughout the year as the rental periods expired, or as beneficiaries chose a contract supplier.

Some contracting suppliers entered into subcontracting agreements with noncontract suppliers to furnish services to beneficiaries. In July of last year, about 31 percent of contracting suppliers had subcontracting agreements. As the CBP allowed, 43 distinct or unique suppliers had contracts for product categories in which they did not have prior experience, and 44 distinct suppliers were awarded contracts in areas where they did not have a prior business location.

CMS's beneficiary access monitoring efforts reported declining inquiries and complaints over the first year of the program, high levels of beneficiary satisfaction, and no changes in health outcomes. Although some of CMS's monitoring efforts have limitations, in the aggregate, they provide useful information to CMS regarding beneficiary access and satisfaction. Medicare claims data from the first 6 months of the Round 1, show that fewer distinct beneficiaries in the areas received DME items in 2011 than 2010 for the six prod-

uct categories we analyzed. However, we do not assume that utilization in 2010 was the appropriate level of Medicare utilization.

Further, the decline in the number of beneficiaries receiving services in 2011 does not necessarily indicate that beneficiaries did not have access to needed DME. It is too soon to determine the full effects on Medicare beneficiaries and suppliers. Although we found that in general, the Round 1 rebid was successfully implemented, our findings are based on the limited data available at the time we did our work. While the prevalence of grandfathered suppliers for some rental items may have ameliorated beneficiary access concerns during the first year, the number of grandfathered suppliers will continue to decline as rental agreements expire.

Likewise, we don't know yet whether any change in the number of subcontracting suppliers will affect beneficiary access. Therefore, more experience with the program is needed, particularly to see if beneficiary access problems emerge. For that reason, it is important to continue to monitor changes in the number of suppliers covering beneficiaries, and trends in utilization.

Mr. Chairman, that concludes my prepared remarks. I would be happy to answer questions.

[The prepared statement of Ms. King follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

For Release on Delivery
Expected at 9:00 a.m. EDT
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MEDICARE

The First Year of the Durable Medical Equipment Competitive Bidding Program Round 1 Rebid

Statement of Kathleen M. King
Director, Health Care

TESTIMONY IS EMBARGOED UNTIL 9:00 AM WEDNESDAY MAY 9, 2012

GAO-12-733T

Chairman Herger, Ranking Member Stark, and Members of the Subcommittee:

I am pleased to be here today to discuss the Medicare[1] competitive bidding program for selected durable medical equipment (DME) and certain other items. My testimony today is focused on our review of the Centers for Medicare & Medicaid Services (CMS)[2] implementation of the competitive bidding program (CBP) round 1 rebid that began on January 1, 2011.

Most Medicare beneficiaries participate in Medicare Part B,[3] which helps pay for DME items, such as oxygen, wheelchairs, hospital beds, walkers, as well as prosthetics, orthotics, and related supplies. Medicare beneficiaries typically obtain DME items from suppliers, which submit claims for payment to Medicare on behalf of beneficiaries. Both we and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) have reported that Medicare and its beneficiaries have sometimes paid higher-than-market rates for various medical equipment

[1]Medicare is a federal health insurance program for people age 65 and older, individuals under age 65 with certain disabilities, and individuals diagnosed with end-stage renal disease.

[2]CMS is an agency within the Department of Health and Human Services that has responsibility for administering the Medicare program.

[3]Medicare Part B helps pay for certain physician, outpatient hospital, laboratory and other services, and medical equipment and supplies—DME. Beneficiaries are required to pay a monthly premium for Part B coverage, an annual deductible, and coinsurance. In general, Medicare beneficiaries pay 20 percent—the coinsurance—of the Medicare fee schedule payment rate for the DME item after reaching their annual Medicare Part B deductible. In 2010, CMS reported that Medicare Part B and beneficiaries paid approximately $14.3 billion for DME and related items.

and supply items.[4] These overpayments increase costs to both Medicare and its beneficiaries.

To achieve Medicare savings for DME, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required that CMS implement the CBP for certain DME. CMS began implementing the first round of the CBP in 2007 and 2008—but 2 weeks after the round 1 began, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) terminated the first round of supplier contracts and required CMS to repeat the CBP round 1—the round 1 rebid. In 2009, CMS began implementing the round 1 rebid, which resulted in the award of contracts to suppliers with payments that began on January 1, 2011. Nine competitive bidding areas[5] and nine product categories[6] for selected

[4]GAO, *Medicare: CMS Has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid*, GAO-10-1057T (Washington, D.C.: Sept. 15, 2010); GAO, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, GAO-10-27 (Washington, D.C.: Nov. 6, 2009); GAO, *Medicare: Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical* GAO-08-767T (Washington, D.C.: May 6, 2008); GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, GAO-04-765 (Washington, D.C.: Sept. 7, 2004); Department of Health and Human Services Office of Inspector General, *A Comparison of Prices for Power Wheelchairs in the Medicare Program*, OEI-03-03-00460 (Washington, D.C.: April 2004); and Janet Rehnquist, Inspector General, Department of Health and Human Services, *Medicare Reimbursement for Medical Equipment and Supplies*, testimony before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, 107th Cong., 2nd sess., June 12, 2002.

[5]The nine CBP round 1 rebid competitive bidding areas are: Charlotte (Charlotte-Gastonia-Concord, North Carolina and South Carolina); Cincinnati (Cincinnati-Middletown, Ohio, Kentucky, and Indiana); Cleveland (Cleveland-Elyria-Mentor, Ohio); Dallas (Dallas-Fort Worth-Arlington, Texas); Kansas City (Kansas City, Missouri and Kansas); Miami (Miami-Fort Lauderdale-Pompano Beach, Florida); Orlando (Orlando-Kissimmee, Florida); Pittsburgh (Pittsburgh, Pennsylvania); and Riverside (Riverside-San Bernardino-Ontario, California).

[6]The CBP round 1 rebid's nine product categories are: complex power wheelchairs (complex rehabilitative power wheelchairs and related accessories—limited to group 2—power wheelchairs with power options); CPAP/RAD (continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories); enteral (enteral nutrients, equipment, and supplies); hospital beds (hospital beds and related accessories); mail-order diabetic supplies; oxygen (oxygen supplies and equipment); standard power wheelchairs (standard power wheelchairs, scooters, and related accessories); walkers (walkers and related accessories); and support surfaces (support surfaces limited to group 2 mattresses and overlays—pressure reducing support surfaces for persons with or at high risk for pressure ulcers—in the Miami competitive bidding area only).

DME items were included in the CBP round 1 rebid. CMS has estimated that the rebid will lead to significant savings for Medicare.

MIPPA also required us to examine particular issues regarding early results from the ongoing CBP round 1 rebid.[7] We reviewed (1) the outcomes of the CBP round 1 rebid process including bid disqualifications and contracts awarded; (2) the effect of the CBP round 1 rebid on DME suppliers; (3) how the CBP round 1 rebid has affected Medicare beneficiary access to and satisfaction with selected DME; and (4) the extent to which the CBP round 1 rebid has affected the utilization of selected DME items.

My remarks today are based on our report, released today, *Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid.*[8] In that report, to examine CBP outcomes and effects, we analyzed data from CMS and its feedback provided to bidding suppliers, analyzed 2011 CBP data about different types of suppliers, and interviewed CMS and CBP contractor officials, DME industry groups, and suppliers. To examine the CBP's effects on beneficiary access, we analyzed Medicare claims data for the first 6 months of 2011, because claims data for those months were the most complete, and compared that data to the same months in 2010. Our findings on the first year of the round 1 rebid are based on the limited evidence available at the time we did our work; more data will become available as the CBP continues. CMS officials commented on a draft of our report. Our work was performed in accordance with generally accepted government auditing standards from May 2011 through May 2012 for both the report and for this statement.

Our work on the outcomes of the CBP round 1 rebid found that the number of bidding suppliers and the number of contracts awarded in the CBP round 1 rebid were very similar to the CBP round 1 and about a third of the 1,011 suppliers that bid in the rebid were awarded at least one CBP contract. CMS made improvements to the bidding process for the CBP round 1 rebid—such as providing additional information about disqualification reasons—and significantly fewer bids were disqualified than in round 1. However, many suppliers still had difficulty meeting bid

[7]Pub. L. No. 110-275, § 154(c), 122 Stat. at 2565-6.

[8]GAO-12-693 (Washington, D.C.: May 9, 2012).

requirements. Of the bids that were disqualified during the initial bid review, 73 percent were disqualified because suppliers failed to provide the required financial documentation or did not meet CMS's minimum financial standard threshold for suppliers.[9] The number of bids disqualified for missing financial documentation in the CBP round 1 rebid would have been higher if many suppliers had not benefited from a MIPPA provision that required that CMS provide suppliers the opportunity to be notified of and to submit missing required financial documentation—a process not available during CBP round 1. As a result, 93 of the 321 suppliers—about 29 percent—that were notified by CMS that they had missing financial documentation, and subsequently provided correct documentation, were ultimately awarded one or more CBP contracts. In the CBP round 1 rebid, as in CBP round 1, CMS determined that some suppliers' bids had been disqualified incorrectly. CMS told us it received bid inquiries from 99 suppliers that had bids disqualified in the CBP round 1 rebid and subsequently extended contracts to 7 of those suppliers that were found to have incorrectly disqualified bids.

During CBP's first year, few contract suppliers—those awarded CBP contracts—had their contracts terminated by CMS, voluntarily canceled their contracts, or were involved in ownership changes. Under the CBP, many non-contract suppliers—those that were not awarded CBP contracts—exercised the option to grandfather certain CBP-covered rental DME items for beneficiaries they were furnishing prior to the implementation of the CBP. Many grandfathered suppliers, for example, continued to furnish the CBP-covered oxygen product category to their beneficiaries. The number of these suppliers generally decreased steadily throughout the first year as CBP-covered beneficiaries' rental periods expired or as beneficiaries chose contract suppliers. Some contract suppliers entered into subcontracting agreements with non-contract suppliers to furnish certain services to CBP-covered beneficiaries. As the CBP allows, some contract suppliers were awarded contracts for product categories that they did not have prior experience in, or for competitive bidding areas where they did not have a prior business location.

CMS's on-going monitoring activities generally indicate that beneficiary DME access and satisfaction have not been affected by the CBP. Although some of these efforts have limitations, in the aggregate, they

[9]These bids may also have been disqualified for other reasons.

provide useful information to CMS regarding beneficiary access and satisfaction. CBP-related calls to 1-800-MEDICARE declined during the first year of CBP implementation. Two percent of calls were from beneficiaries with an urgent need for CBP-covered DME. Of 127,466 inquiries in 2011, CMS classified 151 as complaints.[10] Seventy-seven percent of CBP complaints—or 116 complaints—occurred in the first half of 2011. CMS's pre-and post-implementation beneficiary satisfaction survey did not reveal systemic beneficiary access or satisfaction problems with the CBP, although the survey's questions were limited. For all six questions regarding the CBP, nearly 90 percent of beneficiaries reported their service as being "good" or "very good". Beneficiary satisfaction survey results within competitive bidding areas show a drop of one to three percentage points on each of the six questions from pre-implementation in 2010 to post-implementation in 2011. CMS tracks health outcomes including, for example, hospitalizations, physician visits, and deaths, for beneficiaries potentially affected by the CBP. While the data do not show directly whether outcomes were caused by problems accessing CBP-covered DME, CMS reports no changes in health outcomes for beneficiaries living in competitive bidding areas in 2011.

Medicare claims data from the first 6 months of the CBP round 1 rebid show that fewer distinct CBP-covered beneficiaries[11] in competitive bidding areas received DME items in 2011 than in 2010 for the six CBP product categories that we analyzed.[12] For example, the number of distinct beneficiaries receiving hospital bed product category items in the CBP areas was about 13 percent lower in May 2011 than the distinct beneficiaries receiving these items in May 2010. However, we do not

[10]CMS defines a CBP complaint as a CBP inquiry that cannot be resolved by any customer service representative with 1-800-MEDICARE and is sent to another entity—such as a CMS regional office—for resolution.

[11]Each distinct Medicare beneficiary is only counted once in each of the 6 months analyzed in 2010 and 2011 for each product category in a competitive bidding area, regardless of how many items that beneficiary received.

[12]We did not include these round 1 rebid product categories: (1) the mail-order diabetic testing supplies category due to some beneficiaries switching to non-mail-order sources, a concern being studied by the HHS OIG; (2) the complex power wheelchair category due to potential data reliability concerns reported by a CMS contractor; and (3) the support surfaces category because it is limited to only the Miami competitive bidding area in the round 1 rebid.

assume that utilization in 2010 was the appropriate level of Medicare utilization and the decline in the number of beneficiaries served between 2010 and 2011 does not necessarily indicate that beneficiaries did not have access to needed DME.

Although the first year of the CBP round 1 rebid has been completed, it is too soon to determine its full effects on Medicare beneficiaries and DME suppliers. Although we found that the round 1 rebid was, in general, successfully implemented, our findings are based on the limited data available at the time we did our study and for only the first year of the rebid's contract period. While the prevalence of grandfathered suppliers for some CBP rental items may have ameliorated beneficiary access concerns during the first year, the number of grandfathered suppliers will continue to decrease as rental agreements expire. Likewise, it is not yet known whether any change in the number of subcontracting suppliers will affect beneficiary access. Therefore, more experience with DME competitive bidding is needed, particularly to see if evidence of beneficiary access problems emerges. For that reason, it is important to continue to monitor changes in the number of suppliers serving CBP-covered beneficiaries and trends in utilization of the CBP-covered DME.

Chairman Herger, Ranking Member Stark, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

If you or your staff have any questions about this testimony, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are listed in appendix I.

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact	Kathleen M. King, (202) 512-7114 or kingk@gao.gov
Staff Acknowledgments	In addition to the contact named above, Martin T. Gahart, Assistant Director; Michelle Paluga; Katherine Perry; and Opal Winebrenner were key contributors to this statement.

Chairman HERGER. Ms. King, thank you for your testimony, and I am grateful for the work that GAO has put into examining the performance of this program. As you know, Congress responded to initial concerns about the implementation of Round 1 by stopping it and requiring CMS to rebid it using an improved process. Did Round 1 rebid go more smoothly than the initial Round 1, and were Congress' concerns addressed?

Ms. KING. Yes, they were. The Round 1 rebid was definitely much more smooth than the Round 1, and we evaluated the Round

1, and found a number of significant issues with that, and many of them were resolved. In particular, CMS gave more information about the kinds of financial documentation that were required and gave notice to a supplier when their financial documentation was incomplete. So most of the procedural aspects in Round 1 were definitely ameliorated.

Chairman HERGER. Thank you, Mr. Wilson, I would like to get your reaction to some of the concerns we will be hearing from representatives of the supplier industry later today. One concern is that some suppliers may submit excessively low bids in order to be offered a contract. Some believe there is an additional incentive to submit low bids because bidders are not necessarily required to accept a contract when offered. Can you describe the process that CMS uses to determine which bids are not legitimate, and therefore, disqualified from competing on bid price, and whether the agency plans to expand this bona fide bid review process in Round 2?

Mr. WILSON. I would be happy to address that, Mr. Chairman. That was an issue that we gave serious consideration to in the design and development of the system, and is in fact, the subject of a number of discussions with stakeholders. So for example, we looked at the program and wanted to ensure that bids were bona fide and ensure that we didn't have essentially low-ball bids accepted in the system that would be factored in the price. So we set up a system to essentially screen the bids statistically, and if they were aberrantly low, we would request information from the bidders that would support the price that they bid. We would ask for price sheets, manufacturer invoices, or other information that detailed service requirements in order to support the amount that they bid. And if they could not support that bid price, we actually threw out those bids. We feel that that process worked very, very well.

And so we are carrying that forward to the next two, Round 2 in the 91 areas and actually expanding it. We don't feel as though the lock-in aspect, or issue is necessarily practical and we do have a concern that the statute may not allow us to carry that type of aspect or approach forward within the system. But we don't have concerns because what we found in Round 2, was that essentially 92 percent of suppliers accepted their contract offers. The ones that did not accept their contract offers, essentially their prices were about half above the price or the median, and half below. So we didn't see that as a concern impacting price. That said, I think it is something that we should look at as the program moves forward, and consider.

Chairman HERGER. Another concern we often hear is that because participation in Medicare will be limited to suppliers whose bids are accepted, other suppliers might be unable to stay in business, and there would be less competition when contracts are rebid in future years. What is your reaction to this concern, and could you also comment on why CMS believes it makes sense to limit participation to winning bidders rather than allowing any willing supplier to receive the competitively bid rate?

Mr. WILSON. When we read the statute, it certainly tells us that we can only contract with the winners in the competition to provide

services. But I think there is an important reason for that. If you allowed non-winners to subsequently participate, there would be no incentive to offer value to Medicare and the taxpayers, no incentive to bid a price that truly represented a true market price for the product. And so I think it is important, from an economic sense and from a program savings perspective, and value to beneficiaries, to keep the program the way it is in that regard.

Chairman HERGER. Thank you. Mr. Thompson is recognized for 5 minutes.

Mr. THOMPSON. Thank you, Mr. Chairman. Mr. Wilson, in your testimony, you state that the Round 1 rebid saved about $200 million so far.

Mr. WILSON. Yes, sir.

Mr. THOMPSON. Do those savings accrue to both the Federal Government, and to the beneficiaries?

Mr. WILSON. They do.

Mr. THOMPSON. If so, well, they do, so how much about the Government save, and how much did beneficiaries save?

Mr. WILSON. I think we need to do further analysis of that. What I can tell you today, sir, is that at least $41 million of the $202 million, is direct beneficiary savings in terms of coinsurance. I think there are additional savings that are related to premium offsets, and I would be very happy to get back to you on that particular issue.

Mr. THOMPSON. Okay, thank you. And how much does the average DME user in these areas save? Do you have that number?

Mr. WILSON. Sure, the average price savings, is 35 percent, as I mentioned in my testimony, and so I think that on average, given that coinsurance is 20 percent for beneficiaries, that they would save that 35 percent on their coinsurance.

Mr. THOMPSON. Well, and thanks for the good work of everyone on this committee on both sides of the aisle. The MIPPA strengthen accreditation requirements for all Medicare DME suppliers. Has this requirement helped prevent fraud, waste and abuse within the Medicare program?

Mr. WILSON. I absolutely think it has. It does several important things. It elevates the standards by which suppliers, that suppliers need to meet in order to participate in the program. It also provides for some very, very important clinical requirements that relate to how beneficiaries are—how the items and services are delivered to beneficiaries, how they are educated, and what standard suppliers need to meet for the delivery of very, very important, and critical care items like oxygen and wheelchairs.

Mr. THOMPSON. And how about the so-called illegitimate suppliers? Were you able to weed out some of those as well?

Mr. WILSON. Well, we think that the accreditation program absolutely does that, because again, it sets standards. Accreditation agency goes out and survey suppliers. They need a physical location in order to be surveyed. Information is collected. And so I think that those kinds of standards erect barriers which filter out or stop at the front door some of those illegitimate suppliers.

Mr. THOMPSON. The information that we have suggests that CMS has received about 130,000 beneficiary inquiries, and about 150 beneficiary complaints about the competitive bidding program

in 2011. And as you know, it is important that we figure this one out, and make sure that beneficiary access to necessary suppliers is appropriate. But we also need to make sure that suppliers are complying with the terms of their contracts. So can you give us an example, or any examples of beneficiary inquiry or complaints that indicated supplier access, or quality problems and the actions that your agency took to correct those?

Mr. WILSON. Sure. I would be happy to do that. And the first thing I would say is we are very pleased with the 1–800 response because we heavily marketed 1–800 to our information intermediaries like beneficiary groups and State health insurance programs and many, many others so that we could answer questions about the program and help our beneficiaries get the items and services they need.

I think a good example of how we were able to address some concerns that came up through the call center process may go to wheelchair repairs. We had several instances of beneficiaries not being able to obtain repairs. The supplier was having difficulty getting parts from the manufacturer. We intervened in that process, facilitated a discussion between the manufacturer, the supplier, and the beneficiary in order to make sure the parts could be acquired to fix the wheelchair. And then beyond that, CMS went back and looked at its repair policy and expanded it to allow essentially any supplier to do any repair so that we could stem any future problems like that. So we had a policy response that worked. We had a response for the individual that worked, and I think that that was a very good result.

Mr. THOMPSON. And then in the areas with competitive bidding, there has been some concerns that it has brought about an increased use in hospital care and ER visits. I know you are monitoring this. Can you speak about this complaint and about that increased hospital visit issue?

Mr. WILSON. I would be happy to. We are not seeing increased hospitalizations. We have a very sophisticated monitoring system. We look at the entire competitive bidding area. We look at those beneficiaries that may be in a specific disease group, COPD, emphysema, that may use oxygen for example, that are likely to access the product, and then we look at the specific utilizers of the product. We look at all three cohorts to see if there are any types of concerns which would go to maybe their ability to get to a supplier, or even the quality of the product with looking at the ones that actually utilize it. We are not seeing increases in hospital utilization, hospital admissions compared to the comparator regions.

Mr. THOMPSON. And the ER visits part?

Mr. WILSON. And the ER visits, mortality, any of those important indicators. So we are very pleased with the health outcomes information that we are able to review. And I would just note as well, that we are looking at 100 percent of the Medicare database. We are not looking at a sample. We recreate this every 2 weeks. Policy staff, clinicians, physicians sit down and review this data, and so we are very, very attuned to what is going on and we take the monitoring program very seriously.

Chairman HERGER. The gentleman's time is expired.

Mr. THOMPSON. Yield back.

Chairman HERGER. Thank you, the gentleman from Texas is recognized.

Mr. JOHNSON. Thank you, Mr. Chairman. Mr. Wilson, you said in your testimony CMS has a goal of 30 percent of the contracts go to small businesses, or small suppliers as you call them. Is this an internal goal or requirement by Congress and do you feel 30 percent is an adequate target?

Mr. WILSON. Well, I would just start by saying, Congressman, that we are very pleased with small supplier participation in the program. The statute tells us we need to have at least two suppliers in every competitive bidding area, and it says we need to essentially help or provide opportunities for small suppliers to participate. We have gone way beyond that by setting up networks, or setting up a policy to allow small suppliers to join into networks. A new definition that we worked through with the Small Business Administration about the definition of a small supplier, and then we tied an important policy to that that essentially set a 30 percent target for small supplier participation, whereby, if 30 percent of the winners in a particular competition, in a particular area, by product category, are not small suppliers, we would add small suppliers until we met that target.

That was very successful. We ultimately had about 51 percent of participating suppliers in the first nine areas meeting that definition of the small supplier. So we think that is a very good result.

Mr. JOHNSON. Thank you. Is there any difference between metropolitan and rural?

Mr. WILSON. I am sorry, Congressman, I couldn't quite hear that.

Mr. JOHNSON. Is there any difference between metropolitan areas an rural areas?

Mr. WILSON. There is quite a bit of difference between metropolitan and rural areas.

Mr. JOHNSON. I know that. How do you address it?

Mr. WILSON. Well, we address it in a few important ways. One, we follow the terms of the statute which essentially say we cannot bid in a rural area, so we do not. We also have authority under the statute to essentially carve out of metropolitan areas any low-population density areas. So we have done that in a number of cases so that we are truly looking at integrated urbanized areas where there is a competitive number of suppliers and beneficiaries that will make the program work, generate savings for the program, and patients.

Mr. JOHNSON. Well, I think small businesses are important job creators in this country, and I am pleased to hear that 51 percent of the contracts awarded went to small business. What are you doing to make sure that number holds steady and small businesses will always be part of the competitive program?

Mr. WILSON. Well, we have offered the same opportunities in the current Round 2 of the program that we successfully brought forward in the initial round of the program. And we believe that that 30 percent target will allow us to have a lot of small suppliers participate.

Mr. JOHNSON. You worked with the Small Business Administration several years ago to create the definition of small supplier

for this program, and under this definition of small supplier is a supplier that generates gross revenues of $3.5 million of more—or less in annual receipts, including Medicare and non-Medicare. Do you feel this definition is still an accurate representation of the DME community?

Mr. WILSON. It is the definition that we currently are using. I believe it is still accurate. I think that is a very good question that I would be happy to look into further to see if, you know, potentially it should be revisited, and I will say that we have not revisited it since 2009 so it may be time to do that.

Mr. JOHNSON. Well, why was the definition lowered from your previous standard of $6.5 million?

Mr. WILSON. Well, $6.5 million was the standard for a small business, which is a more general standard. What we wanted to do was specifically target DME suppliers, because that is a narrower definition, or a narrower term of business, and to see what was reflective of that cohort.

Mr. JOHNSON. Thank you. Thank you, Mr. Chairman, I yield back.

Chairman HERGER. Thank you, Mr. Nunes is recognized.

Mr. NUNES. Thank you, Mr. Chairman. Mr. Wilson, I am told that 80 to 90 percent of American businesses are being excluded from supplying Medicare beneficiaries under the competitive bidding model that CMS has implemented in the nine competitive bid areas, and I have three examples here of this. The first one is there were 1,409 suppliers of CPAP respiratory devices and supplies. Now there is 105. That is a 93 percent reduction. The second example is, there were 1,433 suppliers for life-support oxygen, and now, there are 211. That is 85 percent fewer.

If a senior needs a walker, there used to be 1,501 locations to choose from. Now there are just 133. That is about a 94 percent reduction. So I am not an expert here, but given the size of the senior population and the growth and what seems to be a limited number and dwindling number of people being able to win these competitive bids, and then by your own numbers, people who even won the bids backed out, do you know why people that win the bids are backing out?

Mr. WILSON. Congressman, are you referring to the 8 percent that I cited; 8 percent of bidders that did not accept their contracts?

Mr. NUNES. Yeah, why is that happening?

Mr. WILSON. We do not know why they didn't accept their contracts.

Mr. NUNES. Okay, so how it is possible that if you are going to reduce the number of suppliers that seniors won't be impacted? And if the program is working well, why would bidders be pulling out?

Mr. WILSON. We don't know why that very small number of bidders decided not to accept our contract. It could have been for any number of reasons. We have suppliers that come into the program and out of the program all the time. That has always been the case, competitive bidding aside.

I think the thing that I say about looking at the numbers you cited, and looking at this industry, there are a lot of supplier num-

bers, a lot of suppliers providing a small amount of DME. It is not a big part of their business and so the numbers you cited don't really go to full-service DME suppliers that are providing a lot of items, and I will give you an example. I will use Pittsburgh, a place that I am familiar with. In Pittsburgh, there were about, in 2010, about 815 DME supplier numbers. Only 169 were providing more than $10,000 in DME billing, so very small part of their business; maybe a cane, maybe a walker; maybe, you know, a few boxes of test strips, but not a big part of their business. I think seniors will not be impacted because we always award enough contracts to guarantee access.

So when we looked, when we looked back at the 2008 round, what we saw was, we set a demand target that was generous in order to guarantee that beneficiaries would have access and choice, and the actual number of supplies and items delivered, fell far short of that. That way we were absolutely sure that we could guarantee access. We never want to worry about that.

Mr. NUNES. But are you concerned with the three examples that I gave, like 85, to 95 percent reductions in suppliers. That seems like a just a huge change, or are you disagreeing with those numbers, or you agree that has happened?

Mr. WILSON. I can't—I can't tell you if I agree that is happening. I would really have to look at the data. I think what I am saying is that when I looked at the data, I am seeing a much different picture about the composition of the industry, and who is providing a level of service that is important in the marketplace for ensuring access for our beneficiaries. And what I understand is that the great majority——

Mr. NUNES. I will tell you what I will do. I will get you the data that I have, and the examples that I have, and I will get those to you in writing and where I got the data from, and we will see if that matches up with your data, and see if, in fact, the suppliers are reducing dramatically in the marketplace. And so at least then we can clarify here whether there has been an 85, 95 percent reduction in some areas of suppliers. Will that be okay?

Mr. WILSON. I would be very pleased to look at it, sir.

Mr. NUNES. Okay, thank you, Mr. Wilson. Thank you, Mr. Chairman.

Chairman HERGER. Mr. Kind is recognized.

Mr. KIND. Thank you, Mr. Chairman. I want to thank the witnesses for your testimony here today, and Mr. Wilson, start with you. It sounds, based on your testimony, that so far so good. We are seeing some promising significant cost savings without jeopardizing access of care, quality of care, utilization or choices of patients, and you also cited—I wasn't clear what this was referencing—$272 of savings per beneficiary. Is that an estimate of what the beneficiaries were receiving in the last year based on the savings?

Mr. WILSON. That was an example that I used to show what a beneficiary would save in Orlando on a standard power wheelchair.

Mr. KIND. Oh.

Mr. WILSON. Based on coinsurance.

Mr. KIND. Just on a standard power wheelchair in the Orlando market.

Mr. WILSON. Yes.

Mr. KIND. Okay. And the $202 million in savings was a 42 percent reduction from 2010 from the previous year?

Mr. WILSON. That is correct, a straight-line comparison.

Mr. KIND. All right. Well, let me ask you and Ms. King, in regards to, and I think Mr. Nunes was kind of alluding to this in his questioning, is there concerns as we move forward and clearly, we are going to have to be attentive and continue to monitor this program and see how it plays out, but through the competitive bidding process, it is going to lead to greater consolidation and more suppliers dropping out, and getting back to Mr. Johnson's line of inquiry, and the impact on small businesses, is that something we are going to have to keep an eye on; greater consolidation and ultimately losing the power of competitive bidding in certain areas? Why don't you go first, Mr. Wilson.

Mr. WILSON. Thank you. You know, I think we always have to monitor what is going on in the marketplace to ensure that there are no threats or concerns, particularly with respect to beneficiary access. I think we want a viable market. I think what we have tried to do is ensure participation of suppliers even beyond winning a contract, so there is a process for allowing subcontractors. There is a process where grandfathered suppliers, essentially, you can maintain the beneficiaries that you had prior to competitive bidding, and keep those and bill Medicare. There are opportunities to bill other payers. There are opportunities to bill Medicare for things and items that aren't included under the competitive bidding program.

Mr. KIND. A 30 percent figure for small businesses, is that a goal or is that a requirement?

Mr. WILSON. That is a target for us, and the reason why we call it a target, sir, is that it may be that in certain competitions, although this was fairly rare, that there may not be enough small suppliers that won a contract, or bid.

Mr. KIND. Let me ask you something more specific to my area. I represent Western Wisconsin, and Round 2 of the Minneapolis/St. Paul will be part of the competitive bidding MSA area. That leaks into some rural western counties in my congressional district. My concern is, my guess is, that most of the businesses winning the competitive bids are going to come from the Twin Cities area. And my guess again, I could be completely wrong, and getting back to Mr. Johnson, this is going to put the squeeze on a lot of my small suppliers in Western Wisconsin where they won't be awarded the contracts, and might go out of business.

We know that those that win the competitive bids have to service the Medicare beneficiaries, but there is no requirement that they have to service private insurance beneficiaries, including in the surrounding areas of the MSA area. Is that a concern, something that we should keep an eye on as we move forward in Round 2?

Mr. WILSON. Well, on the first part, sir, I think the—we are hopeful that a lot of small suppliers will participate. Based on our experience, we think they will. But we are going to look at that pretty closely. In terms of participating, participation with private insurance, I mean, we are seeing that with a lot of the suppliers currently in the Round 2—in the Round 1 areas. I think if that is

a concern, that is something that we can look into and investigate for you.

Mr. KIND. Yeah, because the counties that I describe in my district are heavily Medicare beneficiaries and so there is a smaller private presence in that. But even in the surrounding MSA area, and not within the MSA itself, the surrounding area, I am going to be, you know, concerned about the impact it is going to have on supplying private insurance beneficiaries through this next round. So that is something that you are sensitive to, or not aware of any potential problems?

Mr. WILSON. Well, we are not aware of any potential problems; did not see any in the Round 1 areas. I think it is a very good point, and something that we can look into, because we do understand it is a broader marketplace and we don't want to have a deleterious effect on those beneficiaries.

Mr. KIND. Right, right. Thank you.

Mr. WILSON. Thank you.

Chairman HERGER. Dr. Price is recognized for 5 minutes.

Mr. PRICE. Thank you, Mr. Chairman. I want to thank the witnesses on a very important topic. Competitive bidding is extremely vital for—the supply of these things for our communities is extremely important. Many of us are concerned about the competitive bidding process. Many of us don't believe that it is actually competitive, and when we talk about canes and wheelchairs, as an orthopedic surgeon, that is one thing, but when you talk about oxygen supply, and CPAP machines, these are life-saving and life-threatening devices if they are not available. So I think it is absolutely vital that we remember the importance of what this means to patients, to patients in the community.

Mr. Wilson, I have got a number of questions and I will follow-up with written questions afterward. But are you aware of how many Round 1 contract winners have gone out of business?

Mr. WILSON. They won a contract and then subsequently went out of business?

Mr. PRICE. Yes.

Mr. WILSON. My understanding, I don't have an exact number for you. We would be happy to provide that, but I understand it is only a handful.

Mr. PRICE. But you have that information?

Mr. WILSON. We do.

Mr. PRICE. Okay, if you could get that to us, that would be great. Does CMS screen the providers to determine whether or not they actually have the capacity to serve the Medicare population in an area?

Mr. WILSON. We do very carefully.

Mr. PRICE. How do you do that?

Mr. WILSON. Well, there are a number of different tools that Medicare uses to screen a provider, both within the competitive bidding program and outside of the competitive bidding program. But we absolutely want to assure the qualifications of a provider. So there are many Medicare requirements, supplier standards that have to be met. We also look at the state licensing, the accreditation program, which relies on quality standards. There is a specific set of qualities.

Mr. PRICE. Many States don't have licensing requirements, mine being one of them. Ms. King, you mentioned, I believe, I didn't see it in your written testimony, but in your oral testimony, you said 44 percent of the contracts were awarded to companies that had previously not served that geographic area. Is that accurate?

Ms. KING. Not quite; 44 suppliers, not 44 percent.

Mr. PRICE. So Mr. Wilson, how, with those 44 suppliers, how do you determine their capacity to serve a population if they are never served before?

Mr. WILSON. Well, they all need to be accredited and meet a set of quality standards. The quality standards include product-specific standards for oxygen, and all other requirements under the Medicare program.

Mr. PRICE. But they have never served that area before.

Mr. WILSON. Well, I don't think that we see a lot of oxygen suppliers that have never provided oxygen before. I think what I would tell you is that 76 percent of all suppliers awarded a contract were experienced in an area providing the—providing the services for which they were awarded a contract.

Mr. PRICE. Are you aware of the number that Mr. Nunes referred to in the nine CBAs, 1,409 suppliers of CPAP and respiratory devices before Round 1. Now there are 105, a 93 percent reduction. This isn't a cane or a hospital bed. These are CPAP machines, respiratory devices, respiratory-assist devices, life and death issues. Are you aware of that number?

Mr. WILSON. I am not aware of that specific number. I can tell you that there were over 950 oxygen suppliers in Miami prior to the competitive bidding program going into effect. We don't think that all of those providers and provider numbers were appropriate.

Mr. PRICE. What if the patients think that one of those that is actually the most responsive in their experience ought to be the one providing their care? Does that come into play?

Mr. WILSON. Well, we want to have patient choice under the program, and so we award more than enough contracts.

Mr. PRICE. Tell me how patient choice is arrived at when you have 1,409 suppliers before CMS intervenes, and 105 afterward. Tell me how that satisfies patient choice.

Mr. WILSON. Well, for the items you mentioned, I would say that those are grandfathered items. They can elect to stay with their current supplier.

Mr. PRICE. And as you know, the problem with that, is that as your program continues, the grandfathering ability to participate and the number of patients that they have dwindles; and therefore, they have much greater difficulty being able to continue their provision to the community.

Mr. WILSON. That is true, but the individual patient can still elect to maintain their relationship with that supplier.

Mr. PRICE. Are you aware of the number that was also quoted by Mr. Nunes, 1,433 suppliers of life-support oxygen; now there are 211, an 85 percent decrease?

Mr. WILSON. I am not aware of that. I am aware of some of the very, very high number of suppliers in certain areas of the——

Mr. PRICE. Understanding that it is patients who are affected by this most directly, not CMS?

Mr. WILSON. We hope—we hope to provide choice for patients, and we hope to judge the qualifications of suppliers so that they meet the standards that allow them to provide.

Mr. PRICE. I would encourage you to reread Ms. King's testimony which says that there is not the information available yet that allows us to draw that conclusion. Thank you, Mr. Chairman.

Chairman HERGER. Thank you, Mr. Buchanan is recognized.

Mr. BUCHANAN. Yeah, thank you, Mr. Chairman. And I want to also thank our witnesses for being here today. Mr. Wilson, back to your term, integrity of bidding. Is it true, that CMS has no mechanism to ensure that suppliers actually have the capacity to meet their claims in terms of their bid? For example, suppliers are not required to provide a letter of credit with a deposit or a surety bond.

I guess I am talking about how do you determine whether a supplier is credible, or viable?

Mr. WILSON. Well, we do have a process put in place by the Congress to ensure that they are viable providers that can meet the terms of their contract.

Mr. BUCHANAN. What is that process? Do you have a letter of credit, or is there a surety bond? Some of the larger suppliers, what, you know, what how do you look at that, just so I know.

Mr. WILSON. There are financial standards required under law, so we do look at a number of different data points, the same types of data elements, financial ratios that banks use to judge viability of either a borrower, or a business. And so we collect tax documents, balance sheets, cash flow. We get credit reports, credit scores, and other information that we can then use to evaluate whether or not the business, that the supplier is viable and able to meet the terms of their contract over a 3-year period.

Mr. BUCHANAN. Also, Mr. Wilson, if a contractor doesn't meet his commitments as a supplier, are there any penalties?

Mr. WILSON. We do have an oversight process that we have used. We want to make sure that suppliers are following the terms of their contract and the regulations, and where they do not, we have intervened with the supplier, we have called in accreditation organizations to do surveys, and we have actually pulled contracts.

Mr. BUCHANAN. Also, just at a conference last year, Mr. Blum stated he was concerned with overutilization. If overutilization is a problem, wouldn't it be more effective to redefine eligibility criteria? In terms of overutilization, that is what we are talking about here. That was his quote.

Mr. WILSON. I think that the accreditation program is a way that Congress put in place as a way of redefining the eligibility criteria for suppliers. I think also the competitive bidding program is another way where we only offer contracts to those that meet financial standards accreditation and offer the best value for Medicare and its beneficiaries.

So I think that has had an effect on overutilization. And in reading the GAO report and looking at our own extensive monitoring, we have seen overutilization come down in the competitive bidding areas; but also, for those requirements that apply more broadly, we

have seen utilization come down in other areas of the country as well.

Mr. BUCHANAN. Mr. Wilson, one other question here. It is my understanding that the CMS has added electrical stimulation devices, TENS, to a list of products included in the recompete. TENS is a noninvasive therapy used by physicians for treating chronic lower back pain. However, effective last month, CMS plans to roll back coverage for TENS devices while they study TENS, which has been approved by the FDA. In fact, it has been approved over the last 30 years. Why not continue coverage of TENS until you guys finalize your studies?

Mr. WILSON. Well, I know that that is a proposed decision upon which we are accepting comments right now, and so it could be that that is given consideration by the folks in our Office of Clinical Standards and Quality. I am not personally working on that issue.

What I would say about adding those devices to competitive bidding is that we are required by law to essentially phase in all items of DME over time, the particular order of which is that those at the highest cost, highest volume. So we are trying to meet the terms of the statute in that regard. However, I would say that we have been talking with our stakeholders about some of the items that we have brought in, received some feedback from some, and I expect to receive more——

Mr. BUCHANAN. Let me just say that there are people that have hundreds of employees, a lot of different firms, that are in the same situation. You create a lot of uncertainty when it has been approved by the FDA for 30 years, and then all of a sudden you cut it back without even completing the study. So I would just suggest that, you know, these are a lot of companies that create jobs, have been in business for some time, and just to create this uncertainty for them, they don't know what exactly to do going forward, because these studies in terms of government could run on for years. So they are very concerned, a lot of them, about this. So I hope that you will take some of their thoughts and ideas into consideration.

Mr. WILSON. I will carry that message back to the folks working on those coverage issues.

Mr. BUCHANAN. Thank you, Mr. Chairman. I yield back.

Chairman HERGER. Mr. Roskam is recognized.

Mr. ROSKAM. Thank you, Mr. Chairman. Mr. Wilson and Ms. King, thank you for your testimony today.

Mr. Wilson, I just wanted to focus in on a couple of the themes you have heard from other members and reflect on some of the concerns that I am hearing from providers in suburban Chicago that I represent.

Could you walk me through the process by which you evaluate a meritorious bid? So, in other words, what happens if you miss it? What happens if you get it wrong? What happens if a bid gets through the process and basically poisons the well and creates something that in fact isn't sustainable? What is the remedy?

Mr. WILSON. Well, let me walk you through the process initially, and I can tell you how we address some of the concerns that have been raised, for example low-ball bids and maybe other issues.

Mr. ROSKAM. Go to low-ball bids, because that is really what I am hearing about.

Mr. WILSON. The first thing we want to do is we want to qualify the supplier. We want to make sure they meet all of Medicare's requirements, State requirements, everything else. We have an extensive process for doing that. So we evaluate the provider and then we scrutinize the bid, and the bid scrutiny starts with our low-ball bid process, something that we worked on with our advisory committee, industry and stakeholder advisory committee going back to the inception of the program.

Essentially we screen out the lowest bids in a product category. We use a statistical measure to screen out the bottom ones. And then we ask the supplier to support that bid by providing information that shows us that they can obtain the product for less than what they bid and allow for the cost of the services to deliver to a beneficiary.

Mr. ROSKAM. Let me just jump in. Have you had any experience where bidders have not been able to fulfill the commitment of their bid?

Mr. WILSON. Well, within the bona fide bid process, we have thrown out bids where they could not document a price.

Mr. ROSKAM. After you have approved it.

Mr. WILSON. Yes.

Mr. ROSKAM. So take the screened ones. I accept at face value that you have that original screening done. Somebody comes in, they meet that screen, and then they come through and as it turns out, they can't do it. Have you had that experience?

Mr. WILSON. We have had that experience where a supplier maybe did not meet the terms of their contract, where they were maybe unwilling to go deliver an item to a beneficiary that was a little bit far from their location or maybe not offering certain services that they should be offering, and we have put them on corrective action plans. This is a handful of cases. If they have not met the terms of that corrective action plan, we have sent in accreditation organizations to resurvey them, and if they have not come back into compliance, then we have pulled their contracts in a handful of cases.

Mr. ROSKAM. Ms. King, you have done the evaluation. My memory is you have done the evaluation of those nine areas, is that correct?

Ms. KING. We have.

Mr. ROSKAM. Did GAO come across any examples of folks that had made a bid and not been able to follow through on the bid based on pricing, in other words, the so-called suicide bids where they come in too low?

Ms. KING. That was not part of our analysis.

Mr. ROSKAM. So you did not even look at that?

Ms. KING. We did not.

Mr. ROSKAM. Okay. Mr. Wilson, going back to you for just a minute, could you speak about—there is some controversy around this bidding process, obviously, and there is a public group of economists and others with some renown that have criticized the bidding process itself.

What is it that animates the hope in you that they are wrong, that all these people that have criticized, it is just like they don't get it? Because it seems to me like there may be something "there" there, and you seem to have an extraordinary amount of confidence. From what does your confidence come?

Mr. WILSON. I think there are two important goals for this program, and a bunch of others, but two important ones. One is to provide a savings for the taxpayers and beneficiaries of Medicare. The other is to ensure that our beneficiaries don't have any negative effects on their health.

Mr. ROSKAM. Agreed completely.

Mr. WILSON. And we have seen—and that access is maintained. We have monitored that very, very closely and have seen that those goals are met. So that makes us pleased with the result that we have.

Beyond that, I think that when a group of economists of the type that we saw writes us a letter, we take it very, very seriously. And we looked at the particular issues that we raised, we talked about them internally with our lawyers and on the policy staff with our leadership to see if those are things that we could do.

I think at the end of the day, at least where we are in the program now, we had some concerns about moving forward with those. One was this lock-in issue, about being able to, if you bid, and you are locked into your contract, you can't turn it down. I think from a practical matter, we don't feel we have the authority to do that, but, more importantly, do we want to lock in a supplier that doesn't want to participate and make them go into a beneficiary's home and give them critical health care services.

Mr. ROSKAM. My time has expired. Thank you.

Chairman HERGER. Mr. Pascrell is recognized.

Mr. PASCRELL. Thank you, Mr. Chairman.

Mr. Chairman, I think that our committee's hearing back in 2008 showed that competitive bidding for durable medical equipment is a place where we can find some agreement, believe it or not. In 2008, when we saw the real problems with the initial incarnation of DME bidding, both sides came together to bring the program back to Earth.

As this program is about to expand to 91 additional metropolitan areas, including northern New Jersey, I would say that we must ensure that beneficiaries continue to have access to lifesaving equipment at affordable prices. But it all comes back to our seniors. This needs to be about delivering the best care to beneficiaries for a lower price.

Prior to implementation, Mr. Wilson, did CMS evaluate how the competitive bidding program would specifically impact patients residing in skilled nursing facilities, nursing facilities and intermediate care facilities? Secondly, what is CMS doing to ensure that these provider settings are not unduly impacted by the competitive bidding program prior to expanding the program to 91 additional MSAs nationwide. Could you answer those two questions, please?

Mr. WILSON. Yes, sir. I think we did focus on the skilled nursing facility setting to see whether there were particular issues that we would need to address to make the program work. Really the only item that is a central concern for skilled nursing facilities

under the DME competitive bidding program are the enteral nutrition services. So we did look at that issue. We did provide for a special category of bidding where a skilled nursing facility could bid to just provide services to their own patients. They wouldn't have to meet the other terms of the contract that other suppliers would.

So we did allow this essentially exceptional process to exist for them, and we have been monitoring that area of the program closely to look and see whether there are concerns with respect to health outcomes for the patients receiving those services in skilled nursing facilities. We are not seeing any concerns right now and we haven't heard any either through the complaint or inquiry process. But if anyone, or you, sir, are hearing those, we would be happy to look into them.

Mr. PASCRELL. So you don't see any impacts that we should be concerned about at this point?

Mr. WILSON. I don't at this time. However, we will continue to monitor that closely as part of the system that we have put in place.

Mr. PASCRELL. Mr. Chairman, I think that we need to follow up, particularly in terms of the impacts of each of these procedures in different specialties within these nursing homes, nursing facilities, and not just the nutritional area. But the other areas you said do not have any concerns of yours?

Mr. WILSON. DME, durable medical equipment as a benefit category under Medicare is not covered in skilled nursing facilities. The skilled nursing facilities under Medicare law are expected to provide those items to their in-patients. So oxygen, wheelchairs, all of the rest are really outside of the program we are talking about today.

Mr. PASCRELL. Okay. Thank you, Mr. Chairman.

Chairman HERGER. Thank you. Mr. Tiberi is recognized.

Mr. TIBERI. Thank you, Mr. Chairman.

Mr. Wilson, I realize that based on your testimony, you see few problems with the current competitive bidding process. In your opinion, why are so many suppliers dissatisfied with this current program?

Mr. WILSON. You know, we do understand that this represents a change for suppliers. We do understand that the program represents reduced prices and less access to the Medicare market. I think what we have tried to do is to work with our stakeholders, suppliers, beneficiaries to understand how we can provide greater access, are there changes we can make to make the program work better but still achieve our goals. But we do understand that there are some fundamental goals in the system that don't always maybe meet their goals.

Mr. TIBERI. There are many that believe that the current program will lead to fewer suppliers sooner, maybe for sure later, meaning less competition and ultimately fewer to supply a growing number of beneficiaries which will lead to higher costs because of the less competition. What do you think about that?

Mr. WILSON. You know, I think we have seen some consolidation in Medicare when you look at different benefit categories and different items. I think there is certainly the potential for some of that here. I think whether that results in a threat to access, I real-

ly don't see that coming. I think there is lots of access in the market now. I expect there will be access to meet the growing beneficiary population.

Mr. TIBERI. Are either of you aware of auction expert and economist Dr. Peter Crampton's recent criticism of the competitive bid process. Has that caused CMS at all to reevaluate?

Mr. WILSON. Yes, and I think I addressed that a little bit earlier. I think we heard the issues coming from the economists that I think wrote this committee and wrote us. Dr. Crampton was the principal economist behind that letter and behind the effort to sort of look at these issues.

We met with him several times to hear his concerns and his ideas. I think at the end of the day, we were moved away from the two issues that he was really concerned about. One is this lock-in issue that I discussed, and the other is median price. We think the program worked well the way we set it up and that there were problems making the changes that he described.

I think one of the fundamental differences here is that we very much view the program as a way to—as more of a Medicare payment system that employs competition, and I think the perspective of Dr. Crampton and the economists' letter is more this should be looked at as a commodities type auction. This is about providing services to patients in the home, and we have held that first.

Mr. TIBERI. So have either of you read the industry's market pricing proposal, and, if so, what do you think?

Ms. KING. It is not something that we have evaluated.

Mr. TIBERI. Okay. Mr. Wilson?

Mr. WILSON. I have been provided a copy of the legislative language and I read that several months ago.

Mr. TIBERI. What do you think?

Mr. WILSON. We have some fairly fundamental concerns with the program as we read that legislative language. I think the first thing that I have mentioned is that when you look at some of the mechanics of the system that they have set up, we believe that it will result in almost universal failures of the auctions that they set up.

Mr. TIBERI. All right. The last question is how much has it cost to implement the competitive bidding program, and did CMS have to hire additional staff?

Mr. WILSON. Yes, sir, CMS hired a few additional staff. I can get you a number in terms of what we have spent so far. I am sorry I don't have that today. When I did an analysis about a year ago, I can tell you that the administrative cost was about .04 percent of the savings that resulted from the program.

Mr. TIBERI. Ms. King?

Ms. KING. That is something that we were asked to look at as part of our work, and we collected some of the operational costs for operating the program and it was partly implemented through contractors, and costs that we were able to identify were about $19.6 million.

Mr. TIBERI. To implement?

Ms. KING. Yes.

Mr. TIBERI. $19.6 million?

Ms. KING. Yes.

Mr. TIBERI. That is a number that will continue to grow, right, as it continues to be implemented, thus far?

Mr. WILSON. It will grow as we expand the program to additional areas, yes, sir.

Mr. TIBERI. And you will get back to me on the number of employees?

Mr. WILSON. I can get you that.

Mr. TIBERI. Thank you.

Chairman HERGER. Ms. Black is recognized.

Mrs. BLACK. Thank you, Mr. Chairman. Let me begin by thanking the chairman for allowing me to sit on the committee and hear the testimony and ask questions. I appreciate that.

I want to just go down the future and look at what is going to happen in the future. So I wasn't able to find in the documentation, I wasn't here earlier for your oral testimony, you may have said this, but how long are these contracts for?

Mr. WILSON. By law, the term is 3 years or fewer. So generally we have used a 3-year term.

Mrs. BLACK. Okay. So we have 3 years worth of contracts. And then after that, we are going to put out bids again and we have already narrowed the pool of bidders. So how do we, going forward, I think you can show up to this point in time, by at least what I see here in this documentation, that there has been some savings. But when you narrow the pool of competitive bidders for the next round, how does that make sense? Now you have less people bidding.

Mr. WILSON. Well, you may have less people bidding. You may have more. I don't any think we know that. I think we still see many, many suppliers in the marketplace continuing to provide services. So I think we are already recompeting Round 1 of the program. We just began that process.

Mrs. BLACK. How do you have more suppliers coming into a program where they can't be reimbursed? Are you talking about subcontractors? Are they then going to be able to bid?

Mr. WILSON. Sure. Subcontractors can bid, suppliers that are providing services maybe through Medicaid programs, those patients, private patients, those providing services that are not yet included in the Medicare program for competitive bidding.

Mrs. BLACK. Ms. King, do you have any feeling on how this will affect future bidding when you narrow the pool?

Ms. KING. I think that it is not something that we have examined, but we think that the program bears watching in the future to see what happens to the number of contract suppliers. But I think also, as Mr. Wilson said, it is not only the people who won in the first round who can bid in the second round. Other suppliers and subcontracting suppliers, new entrants into the market, people serving private beneficiaries will be able to bid in the second round.

Mrs. BLACK. Well, I am concerned about access, and I have heard that. About 50 percent of my district is rural, so there are many of those suppliers that have gone out of business because they said they just, you know, are not able to compete, and I have heard from some of my constituents that they are not getting access the way they were previously. So I do have a concern about that.

But, Ms. King, let me go to you because your report looks at utilization for product categories by comparing the first 6 months of 2010 with the first 6 months of 2011. Does GAO believe that reduced utilization in these MSAs is a sign of access of care being restricted?

Ms. KING. No, we don't necessarily draw that conclusion, because we don't start with the premise that the level of utilization in 2010 was the appropriate level of utilization. And given the fact that there aren't any demonstrated access problems in the first year, you know, we don't think that it necessarily means that beneficiaries did not have access to needed equipment.

Mrs. BLACK. Also then back to you again, Ms. King, the GAO documents the numbers of contract suppliers that have not had previous experience with a product category or geographic area. Are there contract suppliers more likely to subcontract?

Ms. KING. I don't actually know the answer about whether they are more likely to subcontract or not, but 31 percent of contracting suppliers had subcontracts as of the middle of the year last year, so it is a pretty common experience for contractors to have subs.

Mrs. BLACK. I am sorry, what was the percentage?

Ms. KING. Thirty-one percent.

Mrs. BLACK. Okay, 31 percent. So there is no evidence right now that these suppliers are unable to fulfill their contractual agreements from what you have seen?

Ms. KING. No.

Mrs. BLACK. Thank you, Mr. Chairman. I yield back my time.

Chairman HERGER. Thank you. Mr. Gerlach is recognized.

Mr. GERLACH. Thank you, Mr. Chairman. I am sorry, I was out for a constituent meeting there. I am sorry if I ask a question that might have already been posed.

But I was curious about, Mr. Wilson, the mail order diabetic supplies issue. Is that category of product, is that just as it says, mail order diabetic supplies versus a local pharmacist that might have a practice of doing home delivery of diabetic supplies, either to an individual senior's home or to a long-term care facility? Is the mail order diabetic supply that you are part of Round 1 that you were bidding and then providing reimbursement for just mail order?

Mr. WILSON. In the Round 1 program, that is correct, sir. It was just mail order basically through a commercial or government mail carrier, and home delivery and walk-in retail could be treated separately. For the national mail order program that we are rolling out now, our definition of what constitutes mail order will change and essentially we will have deliveries to home through the mail or home delivery through a van, all of that will be subsumed in the national mail order program, although walk-in retail, if someone wants to go in, talk to their pharmacist, get their drugs from the same place they get their diabetic test strips, they will still be able to do that.

Mr. GERLACH. But how will the independent community pharmacist be able to continue to provide that home delivery to a senior that has a very great difficulty getting out of her home to get to the local pharmacy, how will you properly reimburse the local pharmacist for that delivery to make sure that kind of patient access and patient care is maintained?

Mr. WILSON. Well, I think we will be able——

Mr. GERLACH. Will you provide a separate home delivery reimbursement to the pharmacist for doing the home delivery?

Mr. WILSON. Essentially if it is a home delivery, it would have to be accomplished through the national mail order program.

Mr. GERLACH. Okay. But that is not answering my question. My question is, how will you reimburse the pharmacist so the pharmacist can still get out into the home of that patient, see that patient, talk to that patient, answer questions for that patient, without making that patient, who has a very difficult time physically from leaving his or her home and driving X number of miles to the pharmacist, who is not necessarily going to get reimbursed anymore for that home delivery under this new model?

Mr. WILSON. I don't know that our model accommodates that particular situation.

Mr. GERLACH. So is that not then the patient access issue that might have been raised in Ms. King's statement saying that the accessibility issue is not fully vetted here in your review of this situation, and you are not sure of what the impacts might be on patient accessibility and patient care?

Mr. WILSON. What we are talking about in the national mail order is just replacement test strips. So they have their monitor. They can—if they need replacement test strips, that is something that can be sent through the mail. It is a very commodity type of product. That supplier, mail order, that provides it, is required to still be able to educate the patient, answer their questions and provide the services that they would normally get.

Mr. GERLACH. It is my understanding, I have a local pharmacist who supplies supplies to a local long-term care facility, and he delivers a certain kind of supply product that they have requested, a certain kind of testing equipment, testing product. Under this new mail order diabetic supply program that you are going to have, and if it goes to a lower bidder that may use a different kind of testing product than the one that the people at this particular facility want to use, how is that going to be accommodated under that new program? Will they have to accept a testing product that they think is inferior compared to the one that this pharmacist now delivers to that long-term care facility? Will they have to just basically bite the bullet, I guess, and take the more inferior product, because that is the one that was awarded through this program?

Mr. WILSON. I would have to look into exactly how that model would work at a nursing home, but I believe a caregiver at the nursing home could pick up the test strips and bring them back. I will look into that question.

Mr. GERLACH. Can I write to you maybe and give a little more facts and circumstances around that question so you have an opportunity to look at it a little more fully and then can get back to me on that?

Mr. WILSON. I would absolutely appreciate it because I want to make sure there are no concerns here, and if there are some, then I would like an opportunity to address them.

Mr. GERLACH. Thank you. I appreciate it very much. Thanks.

Chairman HERGER. Thank you. I want to thank Mr. Wilson and Ms. King for testifying today. Your insights and perspectives are extremely helpful.

I would now like to invite our second panel of witnesses to step forward so we may hear the supplier and beneficiary perspective on this important issue.

On our second panel of the subcommittee, we will hear from representatives of the stakeholders directly affected by the competitive bidding program. Two of the witnesses are here on behalf of supplier organizations.

Joel Marx is the chair of the Board of the American Association of Homecare, an organization that represents a large number of DME suppliers from around the country.

Wayne Sale is the chair of the Board of the National Association of Independent Medical Equipment Suppliers, which is a national organization that focuses on small mom-and-pop suppliers. We look forward to hearing not only the concerns that these organizations have with the current program, but also what they see as an alternative.

We will also hear from a small business owner, Dino Martis, who is President of Ablecare Medical, Incorporated. Mr. Martis is a Round 1 participant who believes that the current competitive bidding program functions relatively well.

Our final witness is Alfred Chiplin, who is the senior policy attorney at the Center for Medicare Advocacy. We look forward to hearing Mr. Chiplin share the beneficiary perspective. Mr. Marx, you are now recognized for 5 minutes.

STATEMENT OF JOEL D. MARX, CHAIR, BOARD OF DIRECTORS, AMERICAN ASSOCIATION FOR HOMECARE

Mr. MARX. Good morning, Chairman Herger and Members of the Subcommittee. My name is Joel Marx. I have submitted written testimony which I hope will be accepted.

I operate a medical service company which is based in Cleveland, Ohio. We provide virtually all types of home medical equipment and services, including oxygen therapy, wheelchairs and hospital beds. My company was founded by my parents in 1950, and we have grown over the years and are now somewhat larger than the typical provider in our sector. We serve more than 25,000 patients annually through 14 locations in Ohio, Pennsylvania, upstate New York and West Virginia. My company was awarded several contracts under the bidding program.

I am also testifying today as the proud chairman of the board of the American Association for Homecare, which is the primary trade association for providers of home medical equipment. The vast majority of the Association's members are small family operations that, like my company, have served seniors and people with disabilities in their communities for many years.

Let me cut straight to the heart of the issue. We do not oppose a properly designed competitive bidding program for home medical equipment in Medicare. Let me repeat that. We do not oppose a properly designed competitive bid program for home medical equipment. In fact, we favor and strongly endorse a state-of-the-art auction system that would provide true market-based pricing, save ex-

actly the same amount of Medicare and beneficiary dollars that the current bidding system is projected to save, and corrects the fundamental flaws in the current system.

The current system limits Medicare beneficiaries' access to care, it limits choices for consumers, and it will eliminate the Nation's existing network of home care providers, which will ultimately result in hardship and added costs for patients. That would be extremely shortsighted since home care is cost-effective and preferred by patients.

The existing Medicare bidding program designed by CMS distorts the marketplace and the intent of Congress. It radically reduces the number of providers, that is, competitors, allowed to serve Medicare patients, thereby creating oligopolies in the marketplace. It is forcing home care providers to reduce supporting services in order to accept manipulated reimbursement rates obtained through a flawed process. These sufficiencies have been highlighted numerous times before Congress.

More than 240 economists and auction experts, including several Nobel Laureates, have told CMS that significant modifications are needed to fix the current bidding program. More than 30 patient advocacy groups believe that the bidding program as structured today is flawed and needs to be changed. I describe the flaws in the current bidding program in detail in my written testimony, but let me mention a few of them briefly.

The bids are not binding. This is unheard of in any auction system. The pricing calculation uses a median bid rather than a clearing price, and, as CMS has testified, half the bidders bid their best price and ended up with a price lower than that. And there has been a troubling lack of transparency at CMS.

To fix the fundamental flaws in the bidding program, an alternative market-based pricing program for home medical equipment has been proposed by market auction experts and providers. That proposal, known as the Market Pricing Program, or MPP, would require changes to ensure a sustainable program. These changes are consistent with the original intent of Congress and save the same dollars originally expected.

Let me just mention a few key features of the program. It is designed to be budget neutral, and it is now before CBO for scoring. The bids are binding. You stand behind your bid. There are bid bonds, performance guarantees. And only serious bidders will participate and no one will game the system.

The bid price is based on the clearing price, not the median price, which conforms with standard auction design. Reimbursement rates in areas would be adjusted based on the auctions conducted in comparable geographic areas. Rural areas that are currently exempted would remain exempt.

And finally, bid areas would be smaller than metropolitan statistical areas and more homogeneous. Current bidding areas can encompass up to three States with differing laws, regulations and costs. This ensures fairness to smaller community providers.

We strongly urge Congress to pass legislation that would change the current bidding system to a sustainable market pricing program at the earliest legislative opportunity. This will not result in

higher costs to Medicare beneficiaries and will fix a flawed program.

We hope that Congress will take the advice of auction experts, listen to patient advocacy groups and work with the affected stakeholders to create a sustainable bidding system that will serve as a model for other parts of Medicare and not serve as a cautionary tale.

I thank you and would be pleased to answer any questions the committee may have.

Chairman HERGER. Thank you.

[The prepared statement of Mr. Marx follows:]

TESTIMONY IS EMBARGOED UNTIL 9:00 AM WEDNESDAY MAY 9, 2012

Testimony of Joel D. Marx

Chairman, Medical Service Company, Cleveland, OH

On behalf of the American Association for Homecare

Before the Subcommittee on Health

House Committee on Ways and Means

on

Medicare's Durable Medical Equipment Competitive Bidding Program

May 9, 2012

My name is Joel Marx and I own Medical Service Company, a regional home medical equipment (HME) and respiratory care provider based in Cleveland, Ohio. Medical Service Company is a full service home medical equipment provider furnishing virtually all necessary home and respiratory medical equipment and related services to individuals through 14 locations in Ohio, Pennsylvania, New York and West Virginia. We provide home medical equipment and related services to approximately 25,000 patients annually and employ 200 associates.

Medical Service Company was founded in 1950 by my parents with one location and we have grown since then through a combination of excellent patient care and the acquisition of smaller companies that chose to sell their practices in the past few years in the face of numerous challenges. We hold all required licenses, are accredited by the Joint Commission and operate an organization-wide compliance program designed to make sure that we adhere to the increasingly complicated list of laws, rules, regulations and policies concerning the provision of HME to Medicare beneficiaries.

I would like to thank Chairman Herger, Ranking Member Stark and members of the House Ways and Means Subcommittee on Health for holding this hearing on the Medicare competitive bidding program for durable medical equipment, also known as DME or HME, for short. I am pleased to share my experience with the initial round of the Medicare competitive bidding program and make recommendations on how Congress can create a state-of-the art auction program that achieves market

pricing, is sustainable over the long term, will not reduce quality and access to home medical equipment and can be used as a model for other sectors of healthcare.

As a proud member of the American Association for Homecare (AAHomecare), I also serve as volunteer Chairman of the Board of Directors. AAHomecare is the national trade association for home medical equipment service providers, manufacturers and other stakeholders in the homecare community. AAHomecare members serve the medical needs of Americans who require home oxygen therapy, mobility assistive technologies (standard and complex wheelchairs), hospital beds, diabetic testing and medical supplies, inhalation drug therapy, home infusion and other home medical products, services and supplies.

Most of these services and products are already included or will be included in the Medicare competitive bidding program, some without any precedent for doing so. We believe that home medical equipment is a vital component of the continuum of care and is a fundamental component to controlling health care costs by keeping beneficiaries in the most cost-effective and patient preferred setting—their homes—rather than providing acute care in emergency departments and extended care institutional settings. We have grave concerns about the way in which the current bidding program is being implemented and operated.

My goal before this Subcommittee is not to argue against competition. Both the Association and I support healthy and fair competition. HME providers compete every day to provide quality health care items and services to Medicare beneficiaries and embrace the opportunity to continue to compete to serve our patients. My testimony will highlight the flaws of the current competitive bidding program and recommend a sound, budget neutral alternative—the Market Pricing Program for Home Medical Equipment—that can be implemented on the same timeline as the current bidding program.

Today—and even before competitive bidding—we are all reimbursed the exact same amount, and therefore we compete on the basis of the service and quality we offer. Ironically, the same is true in a competitive bidding market, where reimbursement is the same for all contracted providers.

However, we are opposed to the competitive bidding scheme as developed by the Centers for Medicare and Medicaid Services (CMS). The CMS program distorts the marketplace and, by ignoring the pricing methodology used in the original demonstration projects in Florida and Texas and creating restrictive governing policies of the program, goes against the original intent of Congress when it voted to implement the program in 2003. It radically reduces the number of providers (competitors), thereby creating oligopolies in the marketplace at a time when our senior population is growing rapidly. It not only allows bidders to "game" the system's pricing rules but it actually encourages such manipulation during the bidding process. And it forces providers to reduce supportive services in order to meet drastically lower reimbursement rates that were obtained through a fundamentally flawed process.

These deficiencies, which I experienced first-hand as both a contract winner and loser in this program, have been highlighted numerous times before the Congress. Meanwhile, CMS staff touts high cost savings and low negative beneficiary impact. However, the program is only running in nine markets, or six percent of the country. Providers, in the first year of a three-year fixed pricing contract, have been

able to offset excessive and arbitrary price reductions in the bid areas with revenue from non-bid areas. This will prove to be impossible in Round 2 when an additional 91 markets are involved in 2013 and beyond that when CMS applies bidding pricing in non-bid areas, including rural markets like Montana, Iowa, Kansas and even upstate rural New York, where I operate in towns that are as small as those in the Midwest.

AAHomecare does not stand alone in raising concerns with the current program. In fact, well over 200 economists, computer scientists, statisticians and auction experts from around the world have advised CMS that significant modifications need to be made to the bidding program to make it sustainable over time. Moreover, more than 30 consumer and beneficiary groups believe that the bidding program is flawed and needs to be changed.

AAHomecare has worked with auction experts to create an alternative to the current model that would give CMS a sustainable market-based pricing program for home medical equipment. This alternative preserves the concept of competition and ensures future beneficiary access.

The Association has a track record for collaborating with Congress to raise the quality standards for the HME industry and reduce truly improper payments. We have supported mandatory accreditation for providers in our industry, and we have a zero tolerance policy for fraud and abuse as illustrated by our voluntary 13-point plan and formal Code of Ethics. We have supported numerous Congressional anti-fraud efforts, including Congressman Roskam's *Medicare and Medicaid Fighting Fraud and Abuse to Save Taxpayers' Dollars Act* (FAST Act, HR 3399). To help Medicare and its contractors increase payment accuracy, we have increased our educational efforts to improve the industry's compliance with extremely complicated Medicare coverage requirements, which change frequently.

It is with this background that AAHomecare seeks again to be a partner with Congress and CMS to develop a market-based pricing program that is sustainable over the long term and which may serve as a model for other health care sectors. As Congress looks for ways to control health care spending through new and innovative delivery and payment models, I believe we have an obligation to listen to the auction experts who understand auctions best and thereby "get it right."

If we do not address the fundamental flaws in this program now, the hidden cost to beneficiaries will be exorbitant and translate into extended hospital stays, an inability to obtain services when needed in the home and unnecessary trips to the emergency department. The time to fix this program is now.

Cost Effectiveness of Homecare

HME offers an efficient and cost-effective way to allow patients to receive care they need at home. The need for HME and HME providers will continue to grow to serve the ever-increasing number of older Americans. Homecare represents a small but cost-effective portion of the more than $2.3 trillion national health expenditures (NHE) in the United States, and approximately 15.5 million Medicare beneficiaries require some type of home medical equipment annually, from rather simple bedside commodes for people who have hip replacements to high-tech ventilators for quadriplegics.

Yet, not all products are created equal: some require licensed or credentialed clinicians to be on staff or cost $15,000 just to procure. And while Congress and the Office of Inspector General have shed light on products they believe to be overpaid, many others are unprofitable for us to provide even before the bidding program. The high cost of fuel, labor, rent and utilities and regulatory compliance associated with billing and collections, HIPAA privacy, identity theft, IT security, Sarbanes-Oxley, waste disposal, beneficiary and employee safety, OSHA, DOT and FDA regulations continues to escalate year after year. Anyone who has ever required HME or had a relative who needed it can attest that our service includes much more than just the equipment.

The more that people receive quality equipment and services at home, the less that is spent on hospital stays, emergency room visits, and nursing home admissions. Home medical equipment is an important part of the solution to the nation's healthcare funding crisis. The facts bear this statement out as private health care plans have contracted for our services for decades and reaped the cost-savings along the way. Even the current Administration is trying to develop programs to manage chronically ill Medicare patients in the home through new demonstration projects and the Innovation Center.

One key fact that is sometimes lost in this debate is that home medical equipment represents less than two percent of annual Medicare spending. So while this program appears to reduce home medical equipment expenditures when simply comparing past and current Medicare Part B expenditures, CMS has not examined the cost shifting that occurs as a result of the program as more beneficiaries will be forced to receive care in hospitals, nursing homes, and emergency treatments. CMS is also not required to report the total cost of administering the program and yet they have hired hundreds of people and are spending tens of millions of dollars to implement Round 1, with millions more planned for future Rounds. Our alternative auction program ensures that competitive market pricing is still derived while promoting increased access, transparency, fairness and confidence in the program.

Flaws in the Competitive Bidding Program

Experts in the design and operation of market pricing programs have explained in great detail why the CMS bidding program will fail.

CMS is the only group predicting that the program is sustainable over the longer term and operating flawlessly. They are basing this on a short-lived, small sample in nine markets—a program that even CMS officials call a "pilot." Yet, Round 2, with 91 markets, is more than 10 times as complex as Round 1. AAHomecare is on the front lines and can see fundamental flaws that need to be addressed immediately. And 244 experts from across the world have weighed in identifying similar problems and have told CMS, Congress and the Administration that the program will fail. These are our main concerns:

1. **Providers' Bids Are Not Binding Commitments**

In Medicare's bidding program, bidders are not bound by the prices they bid. Any HME provider can decline to accept an offered contract from CMS after the prices, called Single Payment Amounts, are announced by the government. And because of CMS' decision about pricing, 50 percent of all bidders'

prices will be lower than their best submitted bid. Medicare's rule undermines the credibility and integrity of bids, and, without binding commitments, encourages low-ball bids from providers.

To add insult to injury, if HME providers turn down contracts, their bid prices are still included in Medicare's calculation of bid amounts, and other bidders invited to participate are forced to choose between accepting the low price which they did not influence or losing their business altogether by not participating.

CMS states that 92 percent of contract awardees accepted their contract offer. But to decline a contract would immediately imperil a provider's practice because Medicare typically represents 40-60 percent of an HME provider's revenue. Now that we are in year two of the Round 1 program, we are seeing both contracted and non-contracted providers exit the market, change their business model, close down or sell. What has propped this program up is its limited scope—it is being run in only 9 areas across the country. HME providers have been able to subsidize their competitive bidding markets with revenue from non-competitive bid areas. Yet, this cross-subsidization will evaporate as: 1) competitive bidding is expanded to 91 additional areas in 2013, 2) private payors adopt competitive bid rates, and 3) CMS applies bid pricing to non-bid areas, including all rural areas in the U.S., as early as 2015.

2. The Pricing Calculation Is Flawed

Rather than paying contracted providers the clearing price (the last-accepted bid) which is the standard in bidding and reverse auction programs, Medicare's bidding program establishes prices at the unweighted median among the winning bids, resulting in 50 percent of the winning bidders being offered a contract price less than their bids. We know of no other auction or bidding program that has such a perverse rule where bidders are offered contracts at less than the amount they submitted during the bidding process.

3. Composite Bids Are Distorted

A composite bid is an average of a bidder's bids across many products weighted by the government's estimated demand. The composite bid methodology as designed by CMS provides strong incentives to distort bids away from market prices. Only heavily weighted (based on utilization) products within a category will impact the composite bid. Providers can "game" the system by bidding very little off the current Medicare allowable for certain products with little weight while bidding more aggressively on other items with a higher weight. This creates a program where individual products are not closely related to costs and providers participating in the program can "game" the system in order to manipulate the single payment amount. In addition, Medicare set a maximum for all items bid—again distorting the bidding process by not permitting bidders to fairly bid based on their true, fully-loaded costs.

4. Lack of Transparency

CMS has shared virtually no data with the public on the selection of contracted providers, calculation of historical demand (capacity), calculation of the single payment amount for products and services

covered by bidding and outcomes-related findings to evaluate the program. Instead, CMS has made generalized statements that point to the so-called success of the program. Even the Agency's first year update after the implementation of the program is based on generalizations with little data to back up its findings.

Moreover, the savings numbers recently quoted by CMS appear to "double-count" savings resulting from anti-fraud and abuse initiatives that were implemented concomitantly with this program. For example, new provider screening tools, real-time claims monitoring and an avalanche of incremental pre- and post-payment audit activity have been implemented since the program began in 2011. It is surprising and shocking to us that Medicare has elected to audit contract winners in Round One markets so heavily when, in fact, CMS has stated that the program should, on a stand-alone basis, root out fraud and abuse. If this is the case, why deluge contract winners with thousands of audits when those precious resources might be applied to other high-risk healthcare segments and markets?

Under the current program, pricing can be easily manipulated through subjective adjustments to the capacity that a provider lists on its bid forms. During the announcement of the Round One Rebid pricing a CMS official stated the following about contract winners' financial stability. During a press call on July 2, 2010, the CMS official stated –

> *"We do screen bids that are on the low side (to) determine whether or not the provider can actually provide the service or the item at that price," the CMS official said. "That includes looking at invoices...and the provider's financials, including their liquidity and credit, and their ability to expand into a market area. Where we do not feel comfortable, we may not count their capacity at all, or to the degree that they wish us to, in determining the number of winning providers. In fact, we did that 30% of the time. So we have been very careful in selecting praviders and in scrutinizing these bids, in terms of prices and sustainability. I think we're comfortable, when we look at the prices that we see."*

This fact calls into question the validity of the payment rates established by the program and the supposed objective process that CMS established for the program and published in its original Final Rule. The above public comment confirms that CMS may adjust a provider's stated capacity if it questions the provider's bid because it was considered low. By adjusting capacity, CMS manipulated the single payment amount and subjectively decided how many winners were needed. This is completely counter to the more quantifiable rules CMS published initially for the program. The bidding program then just becomes another way to apply administered pricing rather than letting the market set reimbursement rates. The subjectivity is playing with the very viability of numerous family-owned businesses across the country.

5. The Bidding Program Is Designed to Be "Gamed"

Due to the methodology concerning how payment rates are calculated, the impact of non-binding bids and the ability to manipulate the capacity that a provider self reports, the program is built to be "gamed." CMS even appears to acknowledge this fact in its first annual report on the bidding program when they state that, "we are strengthening our bona fide bid review process...to check that very low

bids are sustainable by checking more of those bids." Questioning the sustainability of very low bids implicitly brings into question a program where the single payment amount offered by CMS is, by definition, lower than 50 percent of the accepted bids presented. If the bid amounts represent the lowest pricing while maintaining quality service, how can a program that reduces the pricing additionally be sustainable over the long term?

Under a "win at any cost" program, providers would do well to submit an unreasonably low bid—"a suicide bid"— in order to win a contract. These providers then would be assured of a contract but they must hope that other providers bid more rationally so that the single payment amount would be higher than their submitted bid. From here, providers facing low reimbursement rates could agree to furnish competitively bid items but subsidize their revenue from non-Medicare or non-competitive bidding patients. CMS has never shared with the public how many of the 356 original contract providers have sold their businesses, gone out of business or simply did not bill Medicare for competitively bid items. This is a critical question for Congress to consider, because there were 6,922 unique HME providers submitting claims/providing services in 2010 in the nine bidding areas.

6. CMS Monitoring Is Weak and Non-Transparent

When the bidding program was first implemented, CMS required HME providers to provide the exact brand and model of equipment they were providing to Medicare beneficiaries. CMS also stated that it would begin to measure the patient satisfaction of beneficiaries who received HME services. This equipment report was intended to allow the Agency to determine if contracted providers began to substitute lower quality equipment under the program than was previously furnished to beneficiaries. However, CMS modified this requirement after one quarter into the pilot so there is no way to monitor the quality of equipment Medicare beneficiaries are receiving. And to date, we have seen no beneficiary satisfaction data whatsoever, despite the program's 16-month implementation.

7. No Due Process

Currently, there are no due process protections or appeals processes in place for providers to appeal CMS' methodology for establishing payment rates, making contract awards, designating bidding areas, deciding on the phased-in implementation approach, selecting items and services or the bidding structure and number of contractors. Numerous companies were initially qualified due to a technical error on CMS' fault, and yet it took over 120 days to resolve the issue—a date past the implementation date of 1/1/11.

Fixing the Bidding Program

Congress's objective in requiring Medicare to use a competitive bidding model to establish payment amounts for HME was to reduce Medicare expenditures and ensure that beneficiaries have access to quality items and service. This objective cannot be met because CMS has designed a program that does not hold bidders accountable, does not ensure that bidders are qualified or capable to provide the products in the bid markets, and, due to the arbitrary nature of the capacity analysis, has produced bid rates that are financially unsustainable.

As I mentioned previously, auction experts and economists have warned that the Medicare bidding program is unsustainable in its current form. It will create significant barriers to access and will destroy the HME infrastructure that seniors and people with disabilities depend on as the program expands and providers cannot offset bid pricing with non-bid revenue.

Unfortunately, the recommendations of auction experts, beneficiary and consumer groups, the Medicare Program Advisory and Oversight Committee (PAOC)—the panel created by Congress to advise CMS on the design and implementation of the program—and AAHomecare and other interested groups have not been acted upon. We now look to Congress to fix systemic problems so that Congressional intent is followed.

To fix the fundamental flaws in the bidding program, an alternative market-based pricing program for HME has been developed, which has been specifically tailored to the HME marketplace. The proposal, known as the Market Pricing Program (MPP), would require changes to ensure a financially sustainable program. The MPP uses an electronic state-of-the-art reverse auction to establish market-based reimbursement rates for HME around the country. These changes are consistent with Congress' original intent: to create a program that is based on competition while maintaining beneficiary access to quality items and services. The MPP would be implemented on the same timetable and apply to the same DME product categories as the current program, and will reduce government spending for DME items nationwide. It is intended to be budget-neutral.

The following are key features of the MPP:

1. Timeline

The MPP would be effective on July 1, 2013. The design of the program would be developed through a collaborative, transparent process, involving all stakeholders (HME providers, CMS, beneficiaries), with the guidance of an auction expert and the oversight of the market monitor, to establish market rules, to set market-based and sustainable reimbursement rates, and protect beneficiary access to, and choice, of quality HME products, services, and supplies. The use of an auction expert to help the Secretary of the Department of Health and Human Services design the auction program and a market monitor to help the Secretary ensure that the program is operating effectively and efficiently are common among public auctions.

2. Auction Operation

The MPP would auction a representative 20 percent of the market (counties eligible for bidding) with two-year contracts. The remaining market areas eligible for the program would be served by any eligible providers furnishing HME at the reimbursement rates determined by the auction. The reimbursement rate established through the auction would apply to similar geographic areas (i.e., urban to urban, suburban to suburban) and be adjusted for regional characteristics.

Each year thereafter, the MPP would auction a representative 10 percent of the market (counties eligible for bidding) with two-year contracts starting on July 1 of the year of auction.

An additional 10 percent of eligible market areas would be subject to auction each subsequent year until market pricing programs are occurring in 100 percent of eligible market areas throughout the United States. The process would continue and the Secretary, in consultation with the auction expert, would continue to select additional eligible market areas on an ongoing and rotating basis. **This design would create the most accurate competitive market payment methodology in the Medicare program.**

3. Market Areas

Market Areas established by the Secretary would be composed of a county, an aggregation of counties or parts of counties that together form an economically interdependent area. Large counties would be permitted to be subdivided. The current program's geographic areas are too large to be effective because not all HME providers are able to service an entire area. Smaller contract winners need to subcontract to serve large MSAs and lose quality control since another provider is furnishing the prescribed equipment and related services.

4. Rural Exemption

The same areas that are exempted under the competitive bidding program would be exempted by the MPP.

5. Transparent Process Required

In establishing the MPP, the Secretary would utilize an open and transparent process that includes all relevant stakeholders in the market. Provider and beneficiary education would be required in consultation with the auction expert and market monitor.

6. Market Design

The Secretary would conduct an auction beginning no later than March 2013 and ensure that the market has these basic features:

In each market area, two product categories would be auctioned, producing the clearing price and limiting supplying rights to bid winners. The "lead product" would be submitted for bid in the auction.

Bidders must provide a cash deposit or irrevocable letter of credit (LOC) (from a qualified institution) of 10 percent of expected annual volume as a bid guarantee and winning bidders must provide same as a performance guarantee. Winning bidders must accept a contract (binding bid).

For each product category, a "lead product" is determined by the auction expert on the basis of cost and utilization. Only the "lead product" is bid. The "lead product" sets the pricing for the category and the pricing of all other products in the product category is set relative to the "lead product". The "lead product" is the baseline pricing for the category, and establishes the clearing price. The auction expert will aggregate the various price weighting percentages reported for each product to adopt a single capacity-weighted average. This relative price index will be publicly disclosed in advance of the auction so that each bidder will know how each product price will be determined in the auction.

In the market area subject to the auction, the reimbursement rates of the other "non-lead products" subject to the MPP would be established by reference to reimbursement rates established in economically similar areas in which that product category was subject to auction and all qualified providers able to accept that price would have the right to provide products and related services.

The MPP would use the market "clearing price" (the first excluded bid in each product area) for each product area.

HME providers whose bid is below the "clearing price" would be offered a contract for a two-year period. HME providers whose bids are below the clearing price must accept the contract.

Conclusion

Auction experts have spent more than a year developing changes to improve the current bidding program. AAHomecare stands by and supports the design of the MPP. We strongly urge this Subcommittee and Congress to support this program to establish market pricing for home medical equipment. AAHomecare urges the Subcommittee to secure a cost estimate for the Market Pricing Program and to pass legislation that would change the current, flawed bidding system to a sustainable market pricing program at the earliest legislative opportunity.

Chairman HERGER. Mr. Sale, you are recognized for 5 minutes.

STATEMENT OF H. WAYNE SALE, CHAIR, BOARD OF DIRECTORS, NATIONAL ASSOCIATION OF INDEPENDENT MEDICAL EQUIPMENT SUPPLIERS

Mr. SALE. Good morning and Members of the Committee.

Chairman HERGER. If you could hit the button for your mic, please.

Mr. SALE. I am sorry. Thank you, sir.

Good morning Chairman Herger and members of committee. Thank you for calling this hearing. I appreciate the invitation and the opportunity.

My name is Wayne Sale. I am the chairman of the National Association of Independent Medical Equipment Suppliers, NAIMES. I have been asked to present my observations of the CMS version of Congress' 2003 mandated competitive bidding program and forecast its effect when expanded into 91 additional CBAs.

For many years, I have enjoyed going to auctions and bidding on everything from antiques to cars to artwork. At every one, I registered and was required to stand behind my bid. If I bid on it and I was the last guy to raise my hand, I bought it. If I scratched my head or waved my hand to a friend, I may buy it. So that is how auctions work. The high bidder wins when the buyer is bidding and the low bidder wins when the seller is bidding. Your bid is your word and your word is your bond. How else can it work?

Well, CMS has developed a bidding process that is different. The bid that the sellers of medical equipment submit don't count. They go into a pile and are sorted from the lowest to the highest and CMS picks the one in the middle and assigns it to the product that they are bidding on. If you bid low, below the median price, they may ask you if you want to sell to Medicare, and if you decline, then they go to the next bidder and they ask them. Does that sound like an auction you have ever heard of?

Well, that is the competitive bidding process that CMS has created in response to your 2003 directive. And a taxpayer may ask, did you get what you asked for? I am not an auction expert, but this is not an auction at all. There are no market forces at play here. There is no competition in the pricing mechanism when prices are chosen behind closed doors and then released in a memo that says these are the prices, take them or leave them. CMS has taken years of time and $20 million to develop a competitive bidding system that contains everything but competition.

Oh, those auctions I enjoy going to? I can see who I am bidding against and I know what the bid is and I know what I must do to win. In the CMS bidding process, I have no idea who is bidding or what they are bidding or how to win a product category. All of the bids are submitted through a closed-door process. It takes months and months to hear from them, and, if you win, you don't know how, and if you lose, you don't know why. And it is legal. This federally-funded and congressionally-mandated bidding process is contrived entirely in secrecy and then announced and implemented as if it were the result of a fair competitive price process.

That is the truth, and that is the problem. You are one year into a competitive bidding process that has resulted in administratively assigned prices with zero transparency. There is more to their design that is built to fail, but I only have a minute and a half left,

so let me get to the remedy that we believe will satisfy Congress' mandate.

Today my colleagues and I bring a fix for your consideration. It is called real competition. A real competitive bidding program will work better than an old administrative pricing program. The process we are suggesting is that you replace CMS's bidding scheme with one we call a market pricing plan. It is more like a real auction, where bidders are committed to their bids and the veil of secrecy is eliminated and transparency enters the process to keep it honest. The result will be good prices that will bring more beneficiary access, better beneficiary service, and progressive products and ideas. And a good healthy competition will bring Medicare good prices.

An added benefit to the MPP is its sustainability. It is a program that will last through the challenging times that we have ahead as 78 million baby-boomers march into the Medicare system over the next 30 years. The effects of the implementation of Round 1 competitive bid have not been pretty, nor have they been fully recognized at this point. The reduction of the number of suppliers in each CBA has made equipment and supplies difficult for Medicare beneficiaries to acquire.

My written testimony will tell in greater detail the specifics, but for now, I ask the chairman that I be allowed to submit a CD for the record that contains the testimony of patients who have summoned the will to speak to you whenever you have a chance to listen. Their experiences with this pseudo-competitive bidding will say more than I ever could, and the complaints will grow if this version of competitive bidding is expanded into 91 additional CBAs.

Chairman HERGER. Without objection.

Mr. SALE. Thank you very much, sir. This small industry is only 1.4 percent of the Medicare spending, and it has a lot of potential as a community-based supplier to meet patients' needs. Avoiding expensive hospitalizations is our specialty. Keeping people at home keeps costs low. Don't overlook our value by focusing just on our cost. We can help bring savings to this table and this country. I guarantee it.

Thank you.

Chairman HERGER. Thank you.

[The prepared statement of Mr. Sale follows:]

TESTIMONY IS EMBARGOED UNTIL 9:00 AM WEDNESDAY MAY 9, 2012

Testimony of H. Wayne Sale, Chairman
National Associational of Independent Medical Equipment Suppliers
On behalf of its Members
Before the
House Ways & Means Subcommittee on Health
May 9, 2012 @ 9:00 am

Chairman Herger, Ranking Member Stark, members of the Committee, my name is Wayne Sale, and I am the Chairman of the National Association of Independent Medical Equipment Suppliers (NAIMES). I hail from Virginia's 7th District where Patrick Henry gave his "Liberty or Death" speech, Jefferson built his state house and Chief Justice John Marshall called home. I have been active in this industry for 35 years as a respiratory therapy practitioner and business owner. I currently have a DME and Oxygen business in Central Virginia and employ 30 great people. NAIMES is a volunteer trade association that represents the specific concerns of community based, independent medical equipment suppliers. Our member demographics comprise 96% of the currently active Medicare DMEPOS suppliers, 90% of whom are threatened by this purported Competitive Bidding process.

It is important to begin my comments at the highest level of our country's domestic national concern – the ever-rising costs of healthcare. As medical inflation races ahead of the economy and accounts for higher and higher portions of GDP, we earnestly seek ways to slow its growth and manage our costs. This problem has haunted the budgets and politics of every President and Congress since Medicare's inception. When this hearing concludes, I hope you will leave with a better understanding of how DMEPOS suppliers can contribute to the reduction of those costs.

History

In an effort to curb the costs of Medicare expenditures in 2003, Congress directed CMS, through the Medicare Modernization Act, to employ a formal Competitive Bidding process in order to "reset" Medicare reimbursements for DMEPOS products to achieve "market-based efficiency". This sector of Medicare spending consistently comprised about 2% of the monies annually disbursed. In 2008, the Medicare Improvements and Patient Protection Act (MIPPA) amended CMS's directions for program development slightly, but did nothing to substantially amend the pseudo competitive bidding process that CMS created and controlled behind a veil of secrecy allowed them in 42 USC 1395 w-3(b)(10), the elimination of a program participant's right to an administrative or judicial review.

On February 11, 2009, the DME industry's testimony before the House Small Business Sub-Committee on Rural and Urban Entrepreneurship, pointed out the detrimental effects and unintended consequences of the CMS designed bidding process, and urged the Committee to intervene before re-starting the stalled initial rollout. The industry, patient and expert testimony was not enough to stop the program from being reinstated and on January 1, 2011, CMS's version of pseudo-Competitive Bidding went into effect in 9 Competitive Bidding Areas (CBA's). (Cleveland, OH - Charlotte, NC – Cincinnati, OH – Dallas/Fort Worth, TX – Kansas City, MO/KA – Orlando, FL – Miami/Fort Lauderdale/Palm Beach, FL – Pittsburgh, PA and Riverside/ San Bernardino, CA)

The "competition" that Congress planned to achieve was supposed to occur as suppliers offered the CMS prices at which they could sell the defined products, make a profit, and maintain service to their Medicare patient population. The CMS process of supplier contractor selection, side stepped the "competition" requirement as their program design accepted bids that were non-binding and used the collection of bids offered to choose the price they would assign the product. Apparently, that looked like "competition" to the creators, but in fact, was just another form of administrative price assignment. These contradictions to a genuine competitive bidding process were revealed by several economists, who looked closely at the bidding process created by CMS. Their findings of the program's serious shortcomings were bought to the Congress's attention and CMS leadership directly. Failing to generate sufficient interest to bring the needed change to the program, they thought it imperative to submit their findings and concerns to President Obama in a letter dated June 17, 2011.

Since the commencement of the pseudo-CB in these 9 CBA's, 90% of the suppliers have been removed from the Medicare marketplace, leaving fewer suppliers to service the growing population of Medicare beneficiaries. The elimination of suppliers, combined with the program's forced enlargement of service territories in every CBA, has unquestionably caused distress in the healthcare continuum in the affected areas. Reports of stalled hospital discharges, delays in equipment delivery, and slower response to the delivery of physician ordered equipment have been reported. Suppliers who were not chosen to participate in the contracting process have experienced obvious decreases in referrals and revenues, and subsequently had to lay off workers; an estimated 40% have gone out of business.

While CMS boasts that the savings are mounting from the effects of this program, there are reports generated from FOIA data requests that indicate those savings are being quickly spent at more expensive treatment sites - emergency rooms, hospitals and skilled nursing facilities. These findings have, again, been openly shared with CMS leadership, in an effort to **discern the truth** of how this program is performing at the Medicare beneficiary level. CMS has merely ignored the findings, dismissing them on technical grounds instead of addressing the issues they raise. This conflict of data interpretation is a key point that must be resolved if Congress is to be satisfied with the manner in which CMS has carried out its directives.

The fact that 244 economists from America's most prestigious colleges and universities have examined the CMS bidding design and found it wanting, is not insignificant. (Some of these economists are your constituents) This is NOT a consensus among economists – it is unanimous. Four of the examiners are uncompensated, unbiased Nobel Laureates. Their standards for a successful competitive bidding/auction program design are derived from years of study, scientific trial & error, and market experience around the globe. It is concerning and telling that their knowledge and feedback have been ignored and repelled by CMS for reasons yet to be revealed.

A concern voiced by my membership that exposes a hidden consequence of the CMS design is the fact that some companies that DID get contracts are NOT getting business. The patient referral community – case managers and social workers – have learned that some suppliers were offered contracts for multiple equipment categories and are calling them only, to avoid the time consuming complexity of calling multiple companies to arrange multiple deliveries to establish an adequate treatment site at the patient's home. This effectively eliminates "winning bidders" from the marketplace who accepted a single product contract, reducing the access, choice and service for Medicare beneficiaries, even further.

The most distressing news in the forecast of Competitive Bidding's future is that of the program's unsustainability. There is a high degree of confidence from all parties that the program's design will ultimately lead to failure in the marketplace. Such an aberrant program design has never before been tried or tested. The absence of binding bids, and the assignment of the median bid as the final price, invites foundational weaknesses in the program from the very beginning. The low number of available contracts, and high probability that you won't be offered one, incents bidders to low ball their bid in a desperate act of continuing to participate in the largest insurance program in the world – Medicare.

If the economists are correct and the CMS program design is not sustainable, then neither is the billions of dollars of savings they claim their program will generate. For this reason, it seems realistic to believe that the CMS projected savings are overstated.

The only defense that CMS offers for continuing their version of pseudo-CB is the absence of a significant number of complaints from Medicare beneficiaries. It is clear to my members that there are indeed problems, complaints and concerns. The primary complaint we hear is that people who call the Medicare Hotline to complain, stay on hold for unreasonable lengths of time and eventually give up on registering their complaint. Another reason complaints may not to be heard is that the effected Medicare beneficiary is sick, and tired, and simply doesn't have the energy to go through the process of questioning and explaining and waiting. It's easier and less stressful to find another way to deal with their particular issue than to waste time on the phone.

Round 2 – What's next?

NAIMES leadership has met with CMS management and urged their reassessment of the CB program. Our discussions have been direct and clear as to the predictable outcomes voiced by the auction authorities and the dictates of the rules of market economics. The information submitted to CMS during those discussions, although compelling, have made no impact on CMS's position. It has been clearly stated by CMS representatives that it is determined to carry out Round 2 in similar fashion as Round 1 and looks forward to similar results. That means in 91 US cities, another 90% of the community based DMEPOS suppliers will be eliminated from the Medicare program. As the number of business failures and worker layoffs increase, the number of Medicare beneficiaries will grow almost exponentially. Every day for the next 30 years, approximately 7000 Americans will turn 65 and enter the Medicare system; 78 million, in all.

So, why is CMS intentionally reducing suppliers in the face of rising demand?

With fewer suppliers, and more consumers, how does CMS expect prices to stay low? Laws of economics have soundly established that in a dynamic marketplace, competition among many suppliers keeps prices low, service high, and innovation moving forward. The people who know, say the CMS design will result in higher prices over a short time. In market growth such as the one America will experience in the next 3 decades, a preferred executive plan would be to grow and develop the supplier population to meet the demand. The Baby Boomer demographic has changed every market it has aged through over the last 50 years and those dynamic changes are beginning to trickle into the healthcare industry now.

Over the first 3 years that this version of pseudo-CB is in place, the forced reduction of the supplier population and the increase in market demand promises to raise prices, and again, reduce the CMS projected savings. Said in a more familiar manner, healthcare costs will continue to rise.

If, for all the reasons above, Congress does not stop the implementation of Round 2, we have no reason to believe the findings and ills of Round 1 will not be multiplied by 10. Expanding a poorly designed bidding program will expand the destructive results of that poorly designed bidding program. If we go forward into 100 US cities, perhaps then the volume of beneficiary complaints will be high enough and loud enough for Washington to hear and be moved to act. But, will it then be too late?

Changes are necessary, and sooner is better than later

In order to avert the negative impact and consequences of the current version of pseudo-Competitive Bidding and secure the Medicare DMEPOS benefit sustainability, changes are necessary.

Historic data of Medicare expenditures reveal that, unlike every other category of Medicare spending, Medicare Part B spending in the DMEPOS categories has been practically flat over the last 20 years. Although the industry has experienced an increase in utilization and in the costs of doing business (salaries, gas and employee benefits), US expenditures are consistently less than 2% of the per annum spending. The forced elimination of 1000's of small businesses across the nation from a federally funded program is unimaginable, but that is currently the promise of the future.

NAIMES, in cooperation with a coalition of industry associations, manufacturers and auction experts, have taken a properly designed auction format and created a replacement auction design we have named the "Market Pricing Program" (MPP). An earlier version of this bidding process was tested in a "mock auction" at a trial site on the campus of the University of Maryland in April of 2011. The trial engaged 100 suppliers and a wide variety of associated participants who learned, navigated and" bided" on a list of DMEPOS products, pulled from those used in Round 1. I was in attendance. At the end of the day, the results showed that the mock auction, conducted in the sunshine of transparency, resulted in lower prices for the payer, sustainable market prices for the seller, and market demand being met by a large number of willing participants. Initially, the industry eyed the process with skepticism, but saw that day, that it was a healthy alternative to the pseudo-competitive bidding process imposed by CMS. CMS, CBO and other government agencies was there also and invited to participate. Records of the mock auction are online at http://www.cramton.umd.edu/papers/health-care/

The MPP speaks directly to the short-comings of the current version of non-competitive bidding. Its creators are experts in auction design and, like any good architect, they have followed the known rules of market forces to build a system that will last. The MPP version employs binding bids, performance obligation and national accreditation to assure that suppliers bid to win, make a profit, and stay in business for years to come. The MPP reduces the enormous consumption of time that the current regulatory process requires, and promises to save millions in administrative costs. MPP reduces the geographic size of the CBA's, making them more conducive to prompt service and delivery. And best of all, it achieves sustainable savings and patient choice from a large supplier population ready to meet the growing future demand. Mechanisms have been built into the process that will assure the government gets the best competitive prices, offered by experienced suppliers, willing and able to meet the capacity in their service area. This plan sets the stage for healthy growth in an industry that has proven it can contribute much to the reduction of Medicare spending, particularly in the areas of chronic disease maintenance and prevention of expensive exacerbations.

Since building and launching the MPP is a much less burdensome and time consuming process, the belief is that it could be built in more quickly than the current Round 2 process and be ready to engage the market on a very similar timeline as is currently scheduled. But we must admit, time is of the essence.

What this change would mean to Congress is that the DMEPOS provision of the Medicare Program will be truly competitive, it will save money by enabling patients to be treated at home, avoiding expensive hospital stays, and will cost the Administration less to implement and maintain.

Conclusion

Congress should move to suspend or repeal the current program. If one believes the experts in auction design, and accepts the premise that it could be made better, then a replacement program should be vetted, secured and deployed.

The warnings that the current version of Competitive Bidding will ultimately fail should be taken seriously. The drastic reduction of "supply" in the face of unprecedented national "demand" for home health products and services will bring irreparable harm to the industry and the Medicare population they serve. The sustained concerns voiced and high integrity of testimony is compelling, and should be heeded.

The DME industry takes seriously its personal responsibility to ensure that our nation's seniors have proper access to medically needed, physician prescribed care. We take seriously the opportunity we have to reduce the costs of healthcare to our nation. Both objectives demand that seniors with chronic disease have the DME equipment they need to maintain their health and independence. Utilization of DMEPOS is the most cost effective manner in which to avoid the high cost of hospitalizations incurred by those few chronically diseased patients who consume the most expensive and largest volume of healthcare services. The DME industry brings real, measurable Value to the Medicare Program. Studies and Medicare claims data analysis show savings expressed in terms of Return on Investment to be $6-$10 for every $1 spent. Reductions in ER visits, reductions in hospital stays and reductions in the use of skilled nursing facilities fund the savings and ROI calculated here. That's the Value of the DME benefit to the Medicare Program. If the net savings (ROI) from avoiding the highest priced healthcare services is only $6: $1, the annual total savings that DMEPOS brought to the Medicare

program last year alone is $40 billion – $400,000 billion over 10 years. That's the savings the DMEPOS program achieves by preventing chronic disease from overpowering its host. That's the powerful effect of reducing healthcare expenditures by focusing on disease management, rather than budget management. We must refocus our attentions on the reasons for the high costs of healthcare, and prevent the need to spend at more expensive treatment sites.

In June, 2011, realizing the savings that could be achieved by employing a policy of Prevention, President Obama ordained a National Prevention Strategy, headed by the Surgeon General and signed off on by his entire Cabinet. That Strategy employs the common sense tactics of community based care for chronic diseases as one of its goals because of the obvious savings it will generate. *An ounce of Prevention is worth a pound of cure.* This Strategy is a perfect example of how CMS could and should use its influence and resources to attain higher levels of efficiency using the home health services, equipment and supplies sectors.

Additionally, the Innovation Center of CMS has just released 16 pilot grants under a program called "Independence At Home" which specifically targets COPD and CHF patients with the intention of saving large chunks Part A dollars by using small pieces of Part B dollars. It is a sound program, launched with great anticipation and a focus on chronic disease management to accomplish large savings.

If you include the Hospice and Palliative Care programs as programs installed by CMS that save Medicare by avoiding expensive hospital stays for those with terminally illnesses, then you understand how the hospital beds and oxygen and other durable medical equipment are indispensable tools to accomplish those savings.

Given the Administration's propensity towards Prevention and the obvious savings this strategy already brings to other areas of Medicare spending, there is a golden opportunity, and fiscal imperative, that can be joined together to put the DMEPOS benefit in full competitive gear, and lay the foundation for our country the achieve a more cost effective future.

Recommendations & Requests

We recommend that Congress repeal the current version of the Competitive Bidding Program and replace it with the truly competitive Market Pricing Program.

If further evaluation is necessary before you act, we request that you help facilitate a fuller understanding of the impact of Round 1 by requiring CMS to submit to you the "before and after" 1/1/11 utilization data from the same CBA, as opposed to comparable populations in similar cities that they report now.

If further evaluation is needed, we request that you require CMS to reconcile the differences in their Round 1 data analysis results and the industry's Round 1 data analysis results through FOIA requests. The true effects of this program must be known before expanding it into 91 additional CBAs.

On behalf of Medicare beneficiaries who have complained to us, we request that you require CMS to design and employ a Medicare Help Line that is more efficient and responsive to the needs of our growing Medicare population.

Chairman HERGER. Mr. Martis is recognized for 5 minutes.

STATEMENT OF DINO MARTIS, PRESIDENT, ABLECARE MEDICAL, INC.

Mr. MARTIS. Thank you. Chairman Herger and Congressmen, thank you for inviting me to testify today on the Medicare Durable Medical Equipment Competitive Bidding Program.

I am president of Ablecare Medical. We are a small business based in Cincinnati, Ohio, and we began operations in 1991. We

are a full service respiratory and DME company. Currently we take care of about 3,000 Medicare patients who depend on us to provide their care.

Numerous studies have documented the problems in Medicare's DME benefit; inappropriate reimbursement, fraud, lack of clearly defined services and outcomes. Competitive bidding has brought some pressure to bear on those problems, but concern remains. Fortunately, the debate is no longer centered on whether reimbursement should be reformed, but whether competitive bidding is the right approach.

Based on my experience in Round 1, competitive bidding is working and we are excited about our involvement in this program. In the past, taxpayers and beneficiaries have paid for product that in some instances are tens of times greater than market rates. GAO and the Health and Human Services Inspector General found problems in documenting actual services provided to beneficiaries and the quality of those services. Our industry as a whole was unable to show a positive correlation between prices and clinical outcomes. There are many reasons for this and they have been outlined in my written statement.

It is important to note that reimbursement prior to competitive bidding was not sustainable given continually rising overall health care costs and expected growth in the Medicare and Medicaid population over the next decade. This committee has heard testimony about beneficiaries paying more in cost sharing for certain DME than the typical cost of purchasing that equipment outright.

We have seen that economic hardship has depressed patient utilization of health care services. It has been our experience over the last few years that consumers are reducing demand due to a combination of falling incomes and rising cost sharing requirements. With the introduction of competitive bidding, CMS has reduced the out-of-pocket burden for beneficiaries, many of whom, if not all, are on fixed incomes by lowering the cost of DME and by extension the required beneficiary cost sharing.

From my perspective, the benefit to DME companies is that a greater probability exists that with lower out-of-pocket costs there will be more beneficiaries who are better engaged in their care over the long term as recommended by their physician. This will also increase patient volume, which will, in turn, compensate for loss reimbursement.

In Round 1, we bid on oxygen, hospital beds, PAP, enteral and diabetic supplies. We did not win diabetic supplies. When we bid, our oxygen bid was exactly, in fact to the penny, the same as the current allowable by Medicare. For the other bids, we were 0.05 percent from the current allowables. Competitive bid has forced changes in our business, but it has not reduced patient access or the quality of care.

DME providers take pride in providing quality service services and access and the quality of service provided is market-based. We cannot afford to provide a lesser quality product if we intend to continue in business. We do have to become more efficient. We have recognized that, and we have to use technology. We have recognized that as well.

We commend CMS for the way they have structured the competitive bid process. The agency appropriately provided an opportunity to small- and medium-size businesses to be a part of this program, and they provided these same businesses the flexibility and opportunity to engage with the program as they saw fit.

Our experience suggests that while no single solution will address all the issues generated by the transitioning to competitive bidding or delivery model, I think it would be a mistake to abandon competitive bidding. The alternative system proposed would encourage higher bids and it would mean higher cost sharing for patients. Various studies have shown that as out-of-pocket costs increase, beneficiary engagement and adherence to physician prescription decreases. This is detrimental to the beneficiary, to the DME industry, CMS and the taxpayer.

In the interest of taxpayers, program beneficiaries and the DME industry, we respectfully urge Congress to let this program continue, making adjustments as needed. We stand ready and willing to assist in any effort.

Thank you.

Chairman HERGER. Thank you.

[The prepared statement of Mr. Martis follows:]

TESTIMONY IS EMBARGOED UNTIL 9:00 AM WEDNESDAY MAY 9, 2012

Statement of Dino Martis, President, Ablecare Medical to the Committee on Ways and Means, Subcommittee on Health

Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program

May 9, 2012

Chairman Herger and Ranking Member Stark, I am pleased to provide my thoughts on the Medicare Durable Medieal Equipment eompetitive bidding program. I am the President of Ablecare Medical, Inc., a small business based in Cincinnati and Cleveland, Ohio that began operations in 1991. We have been in business now for 20 years and are a full-service Respiratory and DME company. Currently, Ablecare Medical has 42 employees and strives to efficiently provide the highest quality services to the 3,000 Medicare patients who depend on us to provide their care.

My testimony today is based on my two decades of experience in providing services to America's seniors, both as part of the fee-for-service program and, more recently, as a successful contract awardee in the DME competitive bidding program.

Numerous studies have documented the problems in Medicare's DME benefit: inappropriate reimbursement; fraud; lack of clearly defined services and outcomes. Competitive bidding has brought some pressure to bear on those problems, but concerns remain. Fortunately, the debate is no longer centered on whether reimbursement should be reformed and whether competitive bidding is the right approach. The focus has now shifted to how competitive bidding should be structured moving forward. Based on my experience in rounds one and two, I believe additional modifications should be made to the program, but that these changes are minor.

Competitive bidding is working, and we are excited about our involvement in the program. We remain optimistic the competitive bidding approach holds great potential to improve care while lowering costs. We should also not lose sight of additional reforms that bring competition and technology to bear on the pressing problems of poor outcomes, quality measurement and high costs in DME markets.

Medicare Reimbursement for DME Prior to Competitive Bidding

The Government Accountability Office and others have documented the extent of overpayments for DME over the last two decades. Taxpayers and beneficiaries have paid for products that in some instances are hundreds of times greater than market rates. Likewise, GAO and the Health and Human Services Inspector General found problems in documenting actual services provided to beneficiaries and the quality of those services[1]. Our industry as a whole was unable to show a positive correlation between prices and clinical outcomes. The reasons for this include:

- DME companies are paid separately for clinical services and DME products under fee-for-service. The only incentive to provide clinical services under the fee schedule is if those services are required under a referral.

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[1] See, for example the testimony and reports at: http://www.gao.gov/archive/1998/he98102.pdf; http://www.gao.gov/assets/100/97606.pdf; http://oig.hhs.gov/testimony/docs/2002/020611fin.pdf

- There currently are no standards for measuring how equipment and services affect beneficiary outcomes or treatment costs. Clinical guidelines used by each HME company are different. In part, this may reflect the lack of standardization of clinical processes and measures.

- Industry billing and reporting systems do not necessarily keep track of hospitalizations or disease exacerbations, so it is unclear whether clinical services are positively impacting beneficiary health.

The reimbursement prior to competitive bidding was not sustainable given continually rising healthcare costs and expected growth in Medicare and Medicaid populations over the next decade. As I noted, Medicare reimbursement was well above market rates for both product and any services that could be reasonably provided in delivering the product. This Committee has heard testimony about beneficiaries paying more in cost sharing for certain DME than the typical cost of purchasing the equipment outright. These situations sow distrust in the Medicare program by eroding confidence that Congress and CMS are capable of designing systems to pay for services based on old fashioned commonsense.

Value of Competitive Bidding

As we have seen in other health services, economic hardship has depressed patient utilization of health services. It has been our experience over the last few years that consumers – Medicare and private plan enrollees alike – are reducing demand for provider services in general, and for equipment services in particular, due to the combination of falling incomes and rising cost sharing requirements.

With the introduction of competitive bidding, CMS has reduced the out-of-pocket burden for beneficiaries, many of whom are on fixed income, by lowering the costs of DME and, by extension, the required beneficiary cost sharing. From my perspective the benefit to DME companies is a greater probability that there will be more beneficiaries who are better engaged in their care over the long term because they are using the products as recommended by their physician. This will likely increase volume which, in turn, will compensate for lost reimbursement. The obvious additional benefit is a healthier, more functional beneficiary population.

Our Experience with Round One of Competitive Bidding

Our experience with Round One of competitive bidding was not uniformly positive. While the CMS interface and procedure for bid submissions were reasonably functional, there were instances where the system would go down and we would not be able to enter information required for bid submission. For example, we were unable to bid on the category for walkers. In all fairness, however, we delayed submission of our bids until the last day, and it is possible that others also did the same, creating a spike in server volume that caused intermittent system crash.

We learned from our experience, and in Round Two we entered our bids well in advance of the due date. As a result, we were able to enter our information for all categories for which we intended to submit bids without incident. Thus, the bid submission system in our experience worked as intended.

Competitive bidding has forced changes in our business, but not as commonly reported. Beneficiaries in our Cincinnati and Cleveland bid areas did not lose access or see a drop in service. No competitive bid winner would turn down a referral or provide sub-par service as such business practices would impact their ability to garner future referrals. Competitive bidding has likewise forced changes across our industry, but these changes are no greater than what every other industry experiences when forced to compete. To continue operation, we have had to become more efficient. We have learned how to use technology to our benefit. Manufacturers and other vendors have accepted the inevitability of the new, more competitive system and have made changes to their organizations that have enhanced efficiency. The resulting changes will allow us to reduce our bids and pass those savings onto to taxpayers and beneficiaries.

It is our belief, proven by working in this environment for the last 16 months, that the competitive bid program as structured by CMS will allow us to service all beneficiaries in our area at lower costs and better quality, with no reduction in service. Increased volume replaces what was lost in profit per sale. It is our belief that, as the economy strengthens and beneficiaries feel more financially comfortable, engagement and referrals will return to normal levels and, in fact, increase as more beneficiaries (i.e. baby boomers) enter the Medicare program.

Expectations in Round Two

In Round 2, we bid in those areas in Ohio where we knew we could afford to expand and provide personalized product and service to beneficiaries. Therefore, we did not bid in any area outside of Ohio. Because our experience with competitive bidding has been positive, we are excited about the prospect of expanding our quality services to more Medicare beneficiaries for more products in round two of the competitive bidding program.

Lessons Learned and Room For Improvement

We commend CMS for the way they structured the competitive bid process. The Agency appropriately provided small and medium size companies an opportunity to be a part of the program, when it would have been easier and administratively simpler for them to work exclusively with large companies. CMS also provided an opt-out clause, whereby if we were awarded the bid at a price point that we felt was unreasonable, we were not compelled to enter into a contract with Medicare. This, too, created additional burdens for CMS, but provided suppliers with flexibility and opportunity.

Likewise, we believe the use of subcontracting arrangements is well intentioned, but requires additional program oversight. If a bid winner requires assistance covering demand for product or services, they can contract with non-bid winners or sub-contractors that are Medicare Approved HMEs. This does happen and is good for the bid winners, non-bid winners, CMS,

beneficiaries and for the program's success. In some instances, however, non-bid winners are leveraging their relationship with referral sources to raise costs beyond the normal and customary amount. This impacts bid winners by increasing their operational costs.

While we can understand the rationale for sub-contracting, we do not agree that this is a positive for contract winners, CMS or the patient. Part of the rationale for entering into a competitive bid contract with CMS is the notion of exclusivity. Sub-contracting arrangements not only preclude exclusivity, but also introduces variables detrimental to the beneficiary. For example, because sub-contractors receive only a nominal setup fee and are not directly involved with the patient, they have reduced incentives to provide the best service to beneficiaries. Subcontracting is also more conducive to fraud. For example, a company that did not win a contract could function exclusively as a marketing company, obtain a referral and then provide the patient to a contract winner who would pay them the most for the referral. This puts the contract winner in an untenable position of receiving kickbacks. While CMS has tried to address the issue by requiring referrals to be made directly to the contract winner, frequently it does not function that way on the ground. Most referral sources are still unclear as to what DME competitive bidding really entails. These companies are also fed misinformation by non-contract winners. For example, many non-contract winners inform referral sources, incorrectly, that they can service Medicare patients without divulging that they do so through a contract winner.

We suggest the program should be improved in the following ways:

1. CMS should take immediate steps to inform all current and future DME suppliers and subcontractors about the rules of the road. We believe the Inspector General should issue an advisory opinion to clarify any confusion. Doing so publicly not only would enhance trust in the program, but would quickly dispel incorrect information that leads to potential overspending.

2. CMS also needs to establish a standardized process for reporting on outcomes. As mentioned above, there is little information on the correlation between services provided and patient results.

3. DME competitive bidding should not be a static program. It should evolve as new services, technologies and creative and innovative approaches evolve. We have been involved in an effort to use a technology-based disease identification, prevention and management solution to serve as a model that improves health, improves health care, and reduces healthcare costs for patients with sleep apnea that require DME product. I believe this is the next generation of DME reform: leveraging actual services to improve outcomes while lowering costs.

Conclusion

Our experience suggests that no single solution will address all the issues generated by transitioning to a competitive payment and delivery model. Does that mean we should abandon hope and revert to a failed system that encouraged inappropriate, unnecessary, overpriced, wasteful and potentially harmful care? Absolutely not.

I am also convinced that it would be a mistake to abandon competitive bidding by limiting bidders. Limiting competition encourages higher bids. While that may mean higher profits for the winning bidders, it also translates to higher cost sharing for patients. Some have suggested abandoning reimbursement based on a median price. I believe that approach is also misguided as a median pricing mechanism encourages companies to continue to negotiate price concessions and to perform more efficiently.

In the interest of taxpayers, program beneficiaries and the integrity of the competitive markets, we respectfully urge Congress to let the program continue to play out, making adjustments as needed and as outlined above.

We stand ready and willing to assist the Committee in these efforts.

Chairman HERGER. Mr. Chiplin, you are recognized for 5 minutes.

STATEMENT OF ALFRED J. CHIPLIN, JR., SENIOR POLICY ATTORNEY, CENTER FOR MEDICARE ADVOCACY, INC.

Mr. CHIPLIN. Thank you, Mr. Chairman and Members of the Subcommittee. We have also submitted written testimony for the record.

The subcommittee's continued focus on Medicare's durable medical equipment, prosthetics, orthotics and supplies competitive bidding program is important. We remain cautious about beneficiary access to the scope and quality of DMEPOS items and services as suppliers continue to jockey to do business in this new environment. We think, nonetheless, that if properly implemented, including the development and expansion of appropriate beneficiary education and safeguards, the program could be a positive vehicle for ensuring that beneficiaries get the supplies that they need while holding down cost to the taxpayers.

We are pleased to see that the Medicare agency in its April 2012 assessment of the DMEPOS program is projecting savings to the Medicare Part B trust fund of $25.7 billion between 2013 and 2022 and a reduction in beneficiary and coinsurance amount of $17.1 billion during that same period.

Out-of-pocket savings in the area of the CMS report is the most exciting. We hope over time that the cost savings will increase and that access is not impacted by decreasing costs. As has been cited, out-of-pocket savings have an important impact on access.

We remain concerned that providers carry a range of products within product categories and that beneficiaries are not inappropriately required to change brands or types of items and services in order to stay within cost parameters dictated by the competitive bidding process in local markets. On the whole, we feel that the Medicare agency should be required to step up its efforts to educate beneficiaries about the program, including a special Web site specifically for Medicare beneficiaries.

As to the standards for DME that have been developed, we are pleased to see that they are extensive and comprehensive. We do have a few areas that we would like to see looked at. One is that there continues to be broad monitoring. We would also like to see

that the data that is gathered include information about the level of beneficiary appeals through the appeals process in addition to complaints. Complaints and appeals are different matters. So we would like to see that tightened.

We also would like to see Congress address how it might deal with the suppliers who are not awarded contracts and do continue to provide services in some areas. This, we think, may well be a problem. We would like to have some attention devoted to that.

We also think it is important to give more attention and clarity for beneficiaries on the question of how grandfathering works. It is a complicated area and beneficiaries are often confused. In our work, we hear from beneficiaries more about the confusion about things than anything else at this point, just about how the program will work.

We would also like to see that further analysis from the Medicare agency look at the broader comparison of the number of beneficiary complaints filed. Simply looking at what has come in on the 800 number is not really enough. Over the years, our experience has been that even when serious problems occur, few beneficiaries file complaints and even fewer enter Medicare's administrative process, and we think data analysis should have some mechanism for recognizing this reality.

In conclusion, we remain cautious about the DMEPOS program. We think, nonetheless, that if properly implemented, including expanded beneficiary education efforts and safeguards, the program could be a positive force toward reducing cost to beneficiaries and saving costs to the Nation as a whole.

Thank you very much.

Chairman HERGER. Thank you.

[The prepared statement of Mr. Chiplin follows:]

TESTIMONY IS EMBARGOED UNTIL 9:00 AM WEDNESDAY MAY 9, 2012

Testimony before the

United States House of Representatives

Committee on House Ways and Means

Subcommittee on Health

Medicare's Competitive Bidding Program
For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies: "How the Program Is Impacting Patients, Suppliers, and Program Expenditures"

1100 Longworth House Office Building

Wednesday, May 9, 2012

By

Alfred J. Chiplin, Jr., Esq.
Senior Policy Attorney

Introduction

Mr. Chairman Herger and members of the Subcommittee, I am Alfred J. Chiplin, Jr., Esq., a senior policy attorney in the Washington, DC office of the Center for Medicare Advocacy, Inc. (the Center). We are a national, not-for-profit organization that advocates on behalf of older people and people with disabilities to ensure access to fair, comprehensive, and affordable health care. We are a beneficiary-focused advocacy group. I thank you for the opportunity to come before you this morning.

The Subcommittee's continued focus on Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program is important. We at the Center share your overall concern that the DMEPOS program accomplishes its stated purpose of reducing Medicare costs while protecting beneficiary access to necessary and appropriate items of DMEPOS. Further, we agree that it is of critical importance to assess the Round I experience in the current nine Metropolitan Statistical Areas (MSAs), particularly as the Medicare agency prepares to implement Congress' directive to expand DMEPOS competitive bidding to an additional 91 MSAs in 2013.

We are pleased to see that the Centers for Medicare & Medicaid Services (CMS), the Medicare agency, is projecting savings to the Medicare Part B Trust Fund of $25.7 billion between 2013 and 2022 and a reduction in beneficiary coinsurance amount of $17.1 billion during this same period.[1] These savings are substantial for taxpayers and beneficiaries. We remain cautious, however, about beneficiary access to the scope and quality of DMEPOS items and services as suppliers jockey to do business in this new environment. We urge particular vigilance on the part of the Congress and CMS, particularly as more Metropolitan Statistical Areas (MSAs) are impacted by the DMEPOS competitive bidding program and as more items of DMEPOS become subject to competitive bidding. We think, nonetheless, that if properly implemented, including the development and expansion of appropriate beneficiary education and safeguards, the DMEPOS competitive bidding program could be a positive vehicle for ensuring that beneficiaries get the supplies they need while holding down costs to taxpayers.

In the main, the Center is of the opinion that the DMEPOS competitive bidding program should go forward; that program elements such as grandfathering, smaller supplier networks, and out of network repair and replacement rules could be made more understandable for beneficiaries. In addition, the Medicare agency should step up its efforts to educate beneficiaries about the DMEPOS competitive bidding program, including the development of a website specifically for Medicare beneficiaries. Education efforts should target MSAs as well as geographic areas not yet covered. This is especially necessary as misinformation about the program filters throughout the nation, making for confusion in all geographic areas, including those not currently affected by the DMEPOS competitive bidding program.

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

Recommendations

As my introductory comments reflect, the Center is concerned about beneficiary education and access.

1. The Congress must mandate and the Medicare agency must provide clear information designed and directed specifically to beneficiaries. It can not be merely an add-on to supplier education activities. Necessary information includes defining what beneficiaries will need to know and do when their DMEPOS items need to be repaired or replaced, either in their MSA or while traveling outside that area; how to identify approved suppliers, the forms of acceptable notice; and how to initiate complaints and appeals when problems occur.

2. As we said in our 2010 testimony, CMS must engage in a vigorous and focused campaign to educate the beneficiary community. CMS must step up its educational campaign to ensure that Medicare beneficiaries of all ages are aware of the DMEPOS program and ongoing changes and modifications.

3. CMS must make clear to beneficiaries who reside in geographic areas not currently an MSA or a competitive bidding area (CBA) whether and how the DMEPOS rules affect them.

4. There must be an exploration by the Congress of how to address the caprices of DMEPOS suppliers who do not participate in Medicare yet supply items of DMEPOS. If a supplier is not in an MSA covered by the DMEPOS competitive bidding program, how will Congress and the Medicare agency protect unsuspecting beneficiaries as to notice requirements as well as extend its sanctions and oversight authority?

5. It will continue to be critical to provide clear information when new MSAs – and the CBAs within them – are added to the DMEPOS competitive bidding program. Likewise, there is the need for information for beneficiaries who obtain their DMEPOS products through mail-order suppliers.

6. There needs to be more clarity for beneficiaries about the DMEPOS rules for "grandfathered" suppliers.

7. The Congress and the Medicare agency must continue to speak with a loud and clear voice about the rules of the program, including the limits placed on supplier registration, certification, advertising, and on supplier solicitation of beneficiaries.

8. With respect to beneficiaries, data analysis of the DMEPOS program must look broader than a comparison of the number of beneficiary complaints filed. Over the years, our experience has been that even when serious access to service problems occur, few beneficiaries file complaints and even fewer enter Medicare's administrative appeals process. Data analysis must reflect this reality.

The Center's Ongoing Concerns

Thus far, we have not heard of specific access to DEMPOS problems. We expect, however, that as the program is expanded to the additional 91 MSAs as contemplated, we will hear of more problems. From our experience with other "roll outs" of Medicare changes and additions, we anticipate problems that relate to beneficiaries obtaining DMEPOS and related services from suppliers who are not certified as competitive bidding winners; about beneficiaries not getting adequate notice about the consequences of using suppliers who are not certified through the competitive bidding program; and about beneficiaries having overpaid for items of DMEPOS and for related services, given that they did not obtain their items and services from certified competitive bidding winners.

Access to DMEPOS

On September 15, 2010, I addressed issues of beneficiary access to DMEPOS at a hearing held by the House Energy and Commerce, Subcommittee on Health. The focus of that hearing was on DMEPOS Competitive bidding and implications for Quality, Cost and Access. The issues I raised at that time centered on assuring beneficiary access to necessary DMEPOS and related services and on the need to step up efforts to educate Medicare beneficiaries about the DMEPOS Competitive Bidding program.

In 2010, the Center heard confusion and conflicting conjectures from suppliers and beneficiaries about the consequences of the DMEPOS program, both positive and negative. Even so, our anecdotal experience was that suppliers were applying for certification and complying with the other DMEPOS requirements. What that raised for the Center was the need for clear, concrete, and factual information about the rules of the DMEPOS program and about beneficiary rights and responsibilities. The same is true today.

Access to Information about the DMEPOS program

A big concern in 2010 was that DMEPOS information for beneficiaries was lacking and incomplete and often difficult to find. The "Medicare.gov" website, for example, did not contain information about the DMEPOS competitive bidding program on its home page. Moreover, a search for durable medical equipment on the Medicare.gov website took one to a Medicare Supplier Directory. At that time, when a zip code in a competitive bidding area (CBA) was entered (33394, Ft. Lauderdale, FL, for example), the resulting page did not include information about the new program. And, at that time, the Medicare publication, "What You Should Know if You Need Medicare-covered Equipment or Supplies," revised June 2010, did not appear among the list of publications on the website icon for publications. We were concerned that one would only get to the appropriate section of the CMS website if one entered "DME competitive bidding." Then, as now, few beneficiaries know enough about the DMEPOS program to engage in a sophisticated search in order to obtain basic information.

In 2010, we were concerned that the DMEPOS program has been an enigma for the beneficiary community. Confusion reigned as providers vociferously opposed competitive bidding, including supplier certification, claiming that beneficiaries would not be able to obtain necessary

supplies and services. And, of course, Congressional action requiring that the Medicare agency engage in "Round 1" rebidding added to the confusion.

Limitations of the Medicare Website

I am pleased that once located, there is a fair amount of information available on the Medicare website about the DMEPOS program. Yet, accessing information remains a "scavenger hunt." I find few intuitive beneficiary focused prompts that lead to necessary DMEPOS information. Today, as in 2010, if one knows key words and phrases, one is likely to get to useful information.

I recognize that designing informational tools for beneficiaries about any subject – much less complex information – is not easy. There is no "one-size-fits-all" solution, to say nothing about the need to design materials for different cultures and for multiple languages, as well as trying to account for the various levels of understanding and comprehension that comprise current and future Medicare beneficiaries. Even so, it is important that the agency and the Congress give priority to educating beneficiaries about the DMEPOS program. As it stands, from looking at what has been done thus far, it feels as though educating beneficiaries has not been given the same level of attention as has been directed to the supplier community.

Diabetic testing supplies

The purchase of diabetic testing supplies remains an area of concern. As was noted in my 2010 testimony, under the DMEPOS rules, a Medicare beneficiary who is a permanent resident in a Competitive Bidding Area (CBA) may purchase diabetic testing supplies from a mail order contract supplier that serves the area in which he or she is a permanent resident or from a non-contract supplier in cases where the supplies are not furnished on a mail order basis. For such purchases, the diabetic supplies will be reimbursed at the single payment amount for the CBA where the beneficiary maintains a permanent residence. Moreover, when the diabetic supplies are not furnished through mail order, the suppliers will be paid the fee schedule amount. This process is confusing. It leaves beneficiaries unsure about pricing. Continuous monitoring and oversight is necessary to assure that problems are identified and resolved expeditiously.

In my 2010 testimony, I also emphasized the need for beneficiaries to have good information about their appeal rights – what to do when things go wrong and where they might obtain help in resolving disputes.

Using non-participating suppliers

We anticipate an increase in the number of suppliers who are not in an MSA covered by the DMEPOS program electing to be non-participating suppliers as defined in 42 USC §1395u(i)(2). Some, moreover, will elect not to participate in Medicare. Moreover, Medicare's limiting charge law, 42 USC§1395w-4(g), is not applicable to non-participating suppliers. Rather, the limiting charge law applies only to non-participating suppliers who supply services related to physician services.

Non-participating suppliers in areas not covered by the DMEPOS competitive bidding program are free to require the Medicare beneficiary to submit DMEPOS claims to Medicare and demand payment upfront – they are not subject to a particular written notice requirement – with Medicare reimbursing the beneficiary at the Medicare reasonable charge amount. Significantly, we encountered this very problem in December 2011. It is a problem that leaves the beneficiary responsible to pay the difference between Medicare's reasonable charge reimbursement (or the fee schedule amount) – whichever is less and the non-participating supplier's actual charge. Medicare will reimburse the beneficiary 80% of the Medicare reasonable charge amount (or the fee schedule amount) – whichever is less. The one saving grace for beneficiaries who use non-participating suppliers is that the beneficiary can submit the bill to Medicare and seek as much reimbursement as he or she can get, which, of course, reduces the beneficiary's out-of-pocket costs.

Once the DMEPOS program is fully implemented, and more DMEPOS items and more geographic areas are included in the DMEPOS program, beneficiaries should experience a greater reduction in DME out-of-pocket expenses as they will be required to use certified and registered DMEPOS providers in order to obtain Medicare-covered items of DMEPOS.[2] A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA unless the beneficiary has signed an advance beneficiary notice (ABN). See 42 C.F.R. §414.408(c)(3)(ii) (payment rules DMEPOS).

As we know, the consequences for beneficiaries when using a non-contract suppler are significant. Beneficiaries must be provided information about the importance of obtaining an Advance Beneficiary Notice (ABN) so that they fully understand the consequences of using non-contract suppliers, including possible waiver rights and higher payment rates. For example, contract-suppliers must accept assignment (that is, Medicare's reasonable charge amount, with the beneficiary being responsible for a twenty percent (20%) copayment amount, or the fee schedule amount) if they provide competitively-bid equipment to Medicare patients who reside in a CBA.

Grandfathered suppliers

Using "grandfathered" suppliers remains an issue for beneficiary education. As I stated in my 2010 testimony, Medicare's statutory and regulatory definition of covered DMEPOS suppliers is quite broad. We fear continued confusion among beneficiaries and suppliers about these rules. In many instances, beneficiaries will not know that that their physicians, nurse practitioners, and physical therapists might be subject to the regulations of the DMEPOS program, unless "grandfathered."

[2] Limited CMS data already supports this assumption. See CMS' "Competitive Bidding Update—One Year Implementation Update April 17, 2012, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf., at page 7.

Supplier Calls to Beneficiaries

We have not heard specific problems about the inappropriate use of cell phones, pages, and call-forwarding and other devices while away from their places of business. As more MSAs are in place, we anticipate abuses in this arena. The rules establish a complex scheme for determining whether such use is permitted for purposes of defining working from one's place of business as well as defining supplier networks within a CBA. Ongoing monitoring in this area is essential.

Finding a Supplier

As we noted in our 2010 testimony, we have concerns about DMEPOS program rules that beneficiaries must follow in finding or acquiring a DMEPOS supplier. Our concern remains that the burden on beneficiaries to understand suppler standards and requirements is too much. Even with a massive education campaign, beneficiaries will not be on an appropriate footing with suppliers to ascertain whether a suppler is in compliance with DMEPOS requirements. Under the DMEPOS rules, beneficiaries must change suppliers if their current supplier is not a competitive bidding winner or not otherwise grandfathered. Likewise, sorting suppliers and supplier networks will become increasing more difficult as the DMEPOS program expands, particularly as suppliers with smaller businesses link to form networks as provided under the statute.

Repair and Replacement Concerns

We have heard from advocates that beneficiaries are beginning to raise repair and replacement concerns as their current equipment ages. One concern in particular is about suppliers agreements for repair and replacement for those needing such services when outside the service area in which the DMEPOS was initially obtained. It is imperative that provider agreements, particularly where suppliers are not networked, are specific about responsibilities and clear about what the beneficiary is to do. We remain concerned about the burden on beneficiaries to know and make provisions for possible repairs or replacements in advance of travel. As currently established, repairs and replacements are to be made by the supplier in the CBA in which the beneficiary maintains a permanent residence, unless the supplier or the supplier network has arrangements with certified suppliers in the areas to which the beneficiary will travel.

Permanent residents within a CBA are required to obtain replacement of all items subject to competitive bidding from a contract supplier, including replacement of base equipment and the replacement of parts or accessories for base equipment that is being replaced for reasons other than servicing of the base equipment (for example, the need for a more durable piece of equipment given the beneficiaries weight or equipment usage). As was stated in my 2010 testimony, absent a strong effort to establish a comprehensive beneficiary education effort by the Medicare agency, beneficiaries in this circumstance may face serious access and payment challenges.

An additional repair and replacement concern is that some beneficiaries have complained that their suppliers are changing the products and items they carry and service, frustrating access to certain Medicare-covered items. A rationale for such changes, along with adequate notice to beneficiaries, is necessary.

Additional matters

CMS' April 2012 assessment of the DMEPOS program

Savings

The projected savings announced in CMS' April 2012 assessment is substantial. We hope these savings can be sustained with minimal impact on beneficiary access. Out-of-pocket savings to beneficiaries is an important access mechanism in promoting service and benefit utilization.

Admissions Data

We appreciate the focus of the Medicare agency on "secondary indicators of access to DMEPOS such as hospital admissions, emergency room visits, physician visits and admissions to skilled nursing facilities before and after the implementation of the DMEPOS competitive bidding model."[3] It is, nonetheless, important to state that more research and analysis, form a variety of disciplines and perspectives, is obviously necessary in order to establish a reliable and verifiable correlation between admissions data from specific health care settings and DMEPOS utilization and access.

Complaint Data

It is difficult to rely on the CMS complaint analysis as a measure of how well the DMEPOS competitive bidding program might be working. As said elsewhere in this testimony, few beneficiaries file complaints or enter the Medicare appeals process even when faced with serious access to and denial of service problems. We are not at all surprised at the overall low number of complaints received.[4] Random beneficiary calls are useful, as is adding DMEPOS fields on beneficiary satisfaction survey forms. Moreover, the Medicare agency is still relatively early on in the implementation of the DMEPOS program. Data about the program at this point should be viewed for the limited, but important, value it represents – a current snapshot.

Beneficiary Out-of-Pocket Savings

This area of the CMS report is the most exciting. We hope over time that cost-savings will increase and that access is not impacted by decreasing costs. Similarly, we remain concerned that providers carry a range of products within product categories and that beneficiaries are not inappropriately required to change brands or types of DMEPOS and supplies in order to stay within supplier costs parameters dictated by the competitive bidding process in local markets.

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[3] Ibid., p. 4.

[4] Advocates and beneficiaries find it difficult to get through to the Medicare ombudsman for discussion and review of Medicare problems. Rather, Advocates and beneficiaries are generally shunted back to Medicare's "1-800" number, often experiencing long wait times. In addition, the quality of the information provided when one gets to a "live" person is often uneven.

DMEPOS Supplier Standards

In general, we are pleased to see the level of detail provided in CMS' DMEPOS supplier standards.[5] We think they will be helpful to all concerned. We hope that CMS will take particular elements of these standards and turn them into beneficiary education pieces, using a variety of media and approaches. This could potentially enhance beneficiary knowledge about the DMEPOS competitive bidding program.

Areas of the standards for discussion:

Standard # (b) 11 – Direct solicitation of a Medicare beneficiary

Solicitation of beneficiaries by unscrupulous persons is always a problem. CMS must have in place a comprehensive monitoring approach. The approach should be viewed expansively so as to include new forms of media as they emerge, particularly the internet and the use of so called "smart phones and related devices."

Standard #'s (b) 19 & 20 – Beneficiary Complaint Information

It is imperative to keep good data on beneficiary complaints, including the nature and frequency of the complaints. We are pleased that the standards require the name of the person receiving the complaint, a description of the problem, and a summary of the action taken to resolve the complaint. We are concerned that data about complaint resolution is sufficiently complete to allow an analysis of specific problem areas and the solutions proposed. In addition, we would like to see the data set expanded to include information about the resolution of complaints that are taken through the Medicare administrative appeals process.

Conclusion

We remain cautious about the DMEPOS program, but hope our concerns regarding beneficiary access and information will be addressed to ensure continued positive development of the program for beneficiaries and their families. Likewise, we hope the DMEPOS competitive bidding program will be able to sustain projected cost savings, while reducing fraud, waste, and abuse. We also note the concern of suppliers that use the DMEPOS competitive bidding program as an excuse to make business decisions – unrelated to the program – that adversely impact beneficiary access. Finally, we want to ensure beneficiaries have ready recourse when problems arise. We think, nonetheless, that if properly implemented, including expanded beneficiary education efforts and safeguards, the DMEPOS competitive bidding program could be a positive force toward beneficiaries getting the supplies they need while keeping down costs to taxpayers.

Thank you very much.

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[5] See 42 C.F.R §424.58 (Accreditation – Conditions for Medicare Payment), http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=5558bf6fa8ad4534f53618e3304016c0&rgn=div8&view=text&node=42:3.0.1.1.11.4.6.10&idno=42.

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Chairman HERGER. Mr. Marx, CMS has stated that the Medicare actuaries' estimate that the current competitive bidding program will save more than $25 billion over the next 10 years with the Congressional Budget Office offering a figure in the same ballpark over the same period, realizing that it is challenging the past legislation that increases expenditures. What impact do you expect

that the market pricing program that you support as a replacement would have on Medicare expenditures?

Mr. MARX. Thank you for that question, Chairman Herger. The MPP, Market Pricing Program, is designed to be budget neutral. The Association and the industry supports a program that will keep the same savings for Medicare and beneficiaries through that 10-year program, and we are prepared once we get the scoring to make sure that it does reach that goal.

Chairman HERGER. If CBO were to come back with an estimate showing that MPP would increase spending, would the industry be willing to accept additional reductions to ensure that replacing competitive bidding with MPP is budget neutral?

Mr. MARX. I would not expect that, but we are certainly open to looking at any alternative to fix a flawed program that is going to harm beneficiaries in the long run.

Chairman HERGER. Thank you.

Mr. Sale, your organization has focused on small suppliers and as someone who comes from a small business background myself, I certainly want to make sure that small businesses are able to compete on a level playing field. Considering that CMS set a target for small supplier participation to equal 30 percent, and both CMS and GAO state that actual participation exceeds 50 percent, do you believe that small suppliers are adequately represented in the competitive bidding program?

Mr. SALE. Thank you for that question, sir. I have heard the numbers 30 and 50, 51 percent thrown around today several times. In looking at the Round 1 bidders, there are looked to be around 7,000 bidders. There were 350 or so winners. My membership is comprised of about—well, of those 7,000 bidders, about 96 percent of them are small businesses. So when you eliminate 90 percent of 7,000, you eliminate 6,300 small businesses. The 30 percent of the 350 that they were supposed to hit, they hit 50 percent. So you got 175 of that 350 are small businesses. The rest of larger. Just applying the percentages. It may not be totally accurate.

So the answer is the competitive bidding process leaves a vast majority of small businesses outside of the Medicare program and subsequently, reduces the competition in the marketplace to frightening levels where service, access and innovation we believe will suffer. How could it not?

Chairman HERGER. Thank you. Mr. Martis, I would expect a supplier to be firmly in the camp that higher Medicare fee schedule payment rates are strongly preferable. And I understand you have experienced no significant problems with lower reimbursements that resulted from the competitive bidding program. How was your company able to continue operating while seeing significant reductions in Medicare payments?

Mr. MARTIS. Thank you, Chairman Herger. There are a number of reasons for that. One of the reasons is with the method that competitive bidding was structured, the very same issues that have been brought up here have actually benefited us in higher volumes, so higher volumes have, in fact, replaced the per-service reimbursement reduction.

The second thing that we had to do at our company is, we had to learn how to use technology, and how to become more efficient

in our service provision. That does not mean that we, in any way, decreased service provision to the beneficiary, or the quality of services. It just meant using technology for greater efficiencies.

In fact, in some cases, Chairman Herger, we have increased the provision of equipment to the patient, which has increased the quality of care and has decreased our cost. For example, Dr. Price was mentioning oxygen and PAP as life-saving care. And we have now started to use portable concentrators. We have started to use APAPs instead of just plain CPAPs, which is increasing the quality to the patient, but decreasing our service costs.

Chairman HERGER. Thank you, Mr. Thompson is recognized.

Mr. THOMPSON. Thank you, Mr. Chairman, and thank you to the witnesses for being here. Mr. Chiplin, the savings achieved through competitive bidding, is certainly a preferable proposal than one that would increase cost to beneficiaries, or erode the guaranteed benefits in my view. And I am pleased that this rebid seems to be running much better than the original program, and I am glad that beneficiaries are saving money.

My question to you is, if we went back to the—if we didn't do it this way, would we, in fact, raise cost to beneficiaries or erode the Medicare guarantee, such as premiums support, increased cost-sharing, and income-related premiums? And would you agree that that would be the case, and would have a negative impact on the beneficiaries?

Mr. CHIPLIN. Thank you, Mr. Thompson. In general, yes, I think those are very serious areas of concern.

Mr. THOMPSON. Now, in your testimony before the Energy and Commerce Subcommittee on Health in 2010, you noted that it was difficult to find beneficiary-specific information on CMS's Web site. Is that correct?

Mr. CHIPLIN. Yes, sir.

Mr. THOMPSON. Has CMS addressed these problems?

Mr. CHIPLIN. Well, I did a little homework before coming over, and it is still difficult to find, get to the information. Once you get to the information, it is actually pretty good. It is a big scavenger hunt. That is the term that I use for it. That is why I propose that we have a special Web site that is dedicated to seniors, to beneficiaries that really starts with their concerns and not just an add-on to what we are dealing with with the suppliers. Because their issues and concerns are different, although there are overlaps, but they are basically different.

Mr. THOMPSON. So that would be your recommendation?

Mr. CHIPLIN. Yes, sir.

Mr. THOMPSON. How about, a lot of beneficiaries, Medicare beneficiaries don't have access to the Internet. How do you deal with that universe?

Mr. CHIPLIN. Well, actually, the Medicare population is increasing its access to the——

Mr. THOMPSON. It is increasing, but it is not all there yet.

Mr. CHIPLIN. Is the not all there, but it is certainly on the uptick. I think that you have to educate beneficiaries in a variety of ways. You have to use all kinds of media, written, word of mouth, television, all kinds of things, and also an intergenerational edu-

cation approach, because seniors rely on their family members and children for basic information about all kinds of services.

Mr. THOMPSON. Mr. Marx, I would like to look at the estimated costs of the market pricing proposal, and one of the key elements of your proposal would be higher payments using a clearing price as opposed to the median price, and have you had this scored? Has this been scored? Push the button.

Mr. MARX. The industry has had it scored, but not through CBO yet. It is at CBO awaiting scoring.

Mr. THOMPSON. How is it that you assert that it would be revenue neutral if you haven't yet had it scored?

Mr. MARX. Well, there is an estimated increase in payments going from the market price to the clearing price, but we are expanding the universe of patients, which in Round 2, is going to affect right now in somewhere in the 50 to 60 percent range, and our program expands it to about 70 percent of the Nation, still maintaining that rural exemption. So we are picking up a greater population base at a slightly increased cost, which keeps businesses afloat, and that 3, 4, 5 percent difference will make a difference long-term.

Mr. THOMPSON. But the price would still be higher than under the current program?

Mr. MARX. It will be higher for those in that 50 percent range. It will be substantially lower for the 20 percent of the patients that are added additionally.

Mr. THOMPSON. You had mentioned in your initial remarks that—I think you said bids are not binding.

Mr. MARX. Currently, yes.

Mr. THOMPSON. Currently. I find that difficult to deal with, and I, along with Mr. Sale, believe that once the bid is made and it is accepted, the deal is the deal. And if it is a moving target, it is extremely difficult to do business, and I would think that the beneficiaries are on a little shaky ground as well as far as knowing that they are—that their needs are going to be addressed. Is there anything that you want to add to that nonbinding binding bid?

Mr. MARX. Not only are the bids not binding, March 30th, we placed our bids for the Round 2 locations, and that period is from July 1st, 2013, until June 30, 2016. So not only are the bids not binding, the bids that we are submitting don't even go into effect for 15 months, and then they are in effect for 36 months after that. And how do I estimate my costs for gasoline 4½ years from now? You can't make a valid bid when you have that long a period between the time you placed the bid and the response you get back from the seller.

Mr. THOMPSON. Thank you.

Chairman HERGER. Mr. Nunes is recognized.

Mr. NUNES. Thank you, Mr. Chairman. Mr. Wilson testified in the last panel that essentially everything was going forward, working well, there were no problems and he disputed the letter from the 200 economists who said that this program was not working well and needed to be fixed, changed, in some way.

So who is right? The economists, or Mr. Wilson? We will start with Mr. Marx and I will let you all answer.

Mr. MARX. The economists did not say that the program is affecting beneficiaries today. What they are saying is, the long-term success of the program will ultimately decimate the industry, and you will have an access issue down the road. The pricing that is being used today is less than the best price submitted by half of the providers. So how can they—if they are putting in their best price, and the bid comes back lower than that, how can they maintain that long-term? That is the real issue. And when you only have 6 percent of the population affected by it right now, there is a lot of cost shifting and support from outside of the markets.

Mr. NUNES. What about the examples that we were, that some of us gave to Mr. Wilson, and he disputed the data or seemed not to be aware of the data, how we have reduced 90 percent in terms of the numbers of suppliers. The data that we presented in the questioning that the members of this panel presented to—of the committee presented to the panel, are those, are you aware of these numbers that 90 percent of the suppliers in many areas are basically not able to compete?

Mr. MARX. I am fully aware. That has been ameliorated a little bit by the grandfathering position, which gradually, which allowed existing patients to continue with their existing suppliers up till January 1st of this year. So that is just starting to kick in. Last year existing patients were not disrupted, which was an appropriate decision from the beneficiary's perspective, not forcing them to change providers.

Mr. NUNES. Mr. Sale? Would you like to comment?

Mr. SALE. Yes, sir, thank you for the question. I have heard both sides, and I think the economists are looking at the future growth of the Medicare population, along with the trillions of dollars in unfunded debt that our country is looking at. I think the economists are looking forward and up. I think CMS is looking backward and down at the performance of a program that has lots of numbers that we don't know about, and lots of data that we can't see.

Mr. NUNES. So I want to just to drill down this a little bit. So the CBO number of $25 billion, you don't believe that that savings is going to be realized?

Mr. SALE. I believe that it is forced savings, if it is correct. I tend to think they are inflated.

Mr. NUNES. Maybe meaning that there will be lack of coverage at some point?

Mr. SALE. Well, I don't see how, when you eliminate 90, or 95 percent in your example, of the competitors in the marketplace you can't—you eliminate competition subsequently in every economic example I have seen. Prices go up in such an environment. So yes, I think it is unsustainable. Since the program seems to be unsustainable, certainly the savings would be, I think, overstated, yes.

Mr. NUNES. Okay, Mr. Martis.

Mr. MARTIS. Thank you, Congressman. While I cannot speak to the numbers of the economists, I can speak to what CMS has done with this program. So I would say I think CMS, or since you asked, Mr. Wilson, I think is correct. It has been said that we are depleting competition. We are not depleting competition. While there are

reduced number of providers, the providers that remain are adequately able to take care of the demand and we are also aware of the numbers of participants or beneficiaries that are expected into this system.

I think CMS has done a very good job at deciding what a company's capacity in actuality can be. They had conflicting mandates. I mean, on one hand, we are saying we will give them choice, or we have to give a patient a beneficiary choice; on the other, we are saying, well, we have to also do a bid. In normal bids, the lowest price wins as long as they have a certain accepted quality, and they have a certain accepted capacity. But here we have a number of different providers. I don't believe if we allow every single provider back in, and we reduce costs, I don't believe it is sustainable. I believe it sustainable as it stands today. I think CMS has designed the best program they could within the mandates that they have been given.

Mr. NUNES. Okay, thank you, Mr. Martis. My time is expired. Thank you, Mr. Chairman.

Chairman HERGER. Dr. Price is recognized.

Mr. PRICE. Thank you, Mr. Chairman. Mr. Sale, I just want to commend you for what I think was probably the most eloquent description of the lack of competition in competitive bidding. I think we will probably replay that over and over and over. Mr. Martis, I am struck by your last comment. Do you believe it is the role of the Federal Government to determine how many providers are out there?

Mr. MARTIS. No, sir, I——

Mr. PRICE. You just said that the number of providers that CMS has determined are an adequate number, so I—is my conclusion correct that you believe it is CMS's role to determine how many providers are out there?

Mr. MARTIS. No, sir, I think it is CMS's role to reduce expenses to beneficiaries, to keep the program viable for the beneficiary, and for the DME dealer, and to ensure a certain amount of quality and access to care. I believe they have done that.

Mr. PRICE. And I guess that is my concern, that CMS, a certain amount of quality, which is what I heard you and what I hear CMS talking about all the time. But it may not be the level of quality that the patients desire or want.

Mr. Marx, I was struck by CMS's comment that there were, and kind of offhand comment, that there were some suppliers who "didn't meet the terms of the contract." What does that mean to patients when somebody doesn't meet the terms of a contract?

Mr. MARX. My guess would be that——

Mr. PRICE. Want to turn your mic on please.

Mr. MARX. My assumption would mean that they are not providing the service to the patients that they contracted to provide.

Mr. PRICE. What does that mean?

Mr. MARX. I don't know what Mr. Wilson meant, whether a patient called and asked for a service, and it was too late in the day to provide it, or it was in an outlying area. Those could be areas where the provider let the patient down.

Mr. PRICE. And the service might be a hospital bed, or a walker, or a cane, but it might be an oxygen supply.

Mr. MARX. Oh, it could be oxygen. It would be CPAP. It could be life-sustaining items.

Mr. PRICE. Life-sustaining items?

Mr. MARX. Yes.

Mr. PRICE. So when CMS selects suppliers who don't necessarily meet "the terms of the contract," that could be life-threatening to patient?

Mr. MARX. Yes, it would be life-threatening.

Mr. PRICE. I am impressed by this MPP, the Market Pricing Program that has been proposed that you all have proposed, because I think that it gets to the same level of savings in a way that provides much more efficient and higher quality, and more responsive care to patients as well as continuing to allow for innovation. Would you take a little time and just describe the Market Pricing Program for us?

Mr. MARX. The Market Pricing Program is an auction program run by auction experts. It is proposed to be run electronically through an iterative process that reduces the pricing down to a true cost to do business. It is competitive. It allows multiple contracted providers, and it requires that if you want to bid, you have to be viable, you have to have a bid bond, a performance guarantee. If you bid it, and the pricing is above your bid, you will contract or forfeit your bid bond.

It makes a fair pricing program, but it also preserves the choice of consumers. It keeps a larger population of local providers. It reduces the size of the bid area, whereas in an area of Cincinnati, there are three States the provider must serve to serve patients in that contract: Ohio, Kentucky and Indiana. They are all part of that competitive bid area, and for a small provider to be licensed in three States and meet three States' regulations and a territory that could amount to 80 or 100 miles across, it is very difficult.

The MPP reduces the size of the markets so that local providers can serve their local community as they have done for years.

Mr. PRICE. So by exclusion of the small local providers CMS, by design of their program, CMS is, in essence, decreasing the responsiveness and the ability for patients to receive the care that they received in the past. Would you agree with that statement?

Mr. MARX. I do.

Mr. PRICE. Thank you, Mr. Chairman.

Chairman HERGER. Thank you. Mr. Tiberi is recognized.

Mr. TIBERI. Thank you, and thank you for allowing me to be here today, Mr. Chairman, to participate in this hearing. Mr. Marx, do you believe that allowing bids to be nonbinding encourages low-balling?

Mr. MARTIS. Congressman, if a provider would like to low-ball, yes, the answer is yes, it could. I don't know whether it encourages low-balling, but a submission of a low-ball bid is possible. However, my understanding of what CMS did in this bid process, is they took out the outlier bids, the highest and the lowest, and tried to come to a median bid on the remainder.

My own personal experience, what we did with our company, is, as I stated before, for the majority of the bids, or actually all of the bids, except for oxygen, where we were dead-on. For all of the other bids, we are .05 percent away from the current allowed amount. So

I don't see why providers would low-ball the bid to a level where they know they can't provide service.

Mr. TIBERI. Did you enter into all contracts that you were awarded?

Mr. MARTIS. Did we enter all contracts that we were awarded, sir? Yes, we did.

Mr. TIBERI. Were the payment amounts adequate to cover the project categories that you talked about that you were involved in?

Mr. MARTIS. We believed so, because as I said, Congressman, we were .05 percent away from the allowed amount, so yes.

Mr. TIBERI. Do you plan on participating into Round 2, and if so, like areas like Columbus, Ohio?

Mr. MARTIS. We do, yes, sir.

Mr. TIBERI. So you plan on participating?

Mr. MARTIS. Yes, sir.

Mr. TIBERI. Mr. Sale, you talked about this process of Market Pricing Program, or this new proposal. Would it have similar effects on reducing expenditures and beneficiary costs in your opinion?

Mr. SALE. Would it have effects on reducing what, sir?

Mr. TIBERI. Beneficiary cost, and cost to Medicare's over all expenditures that CMS argues their current process does?

Mr. SALE. I certainly think it would reduce the expenditures from where they are now, and I think 20 percent of that is going to reduce and save beneficiaries. I would like to say, though, that the 20 percent coinsurance that is left after Medicare has paid its 80 percent, generally is paid by insurance companies. We talk about beneficiary savings, but 89 percent of my patient population that is Medicare, has a coinsurance; some through, you know, any other the Anthems, the AARPs. So they pay a monthly premium to someone to cover that $17 billion.

So I would like to nullify the fact that these are really beneficiary savings. In many cases, these are insurance savings, and if you put that into context, the answer is both numbers will go down, yes.

Mr. TIBERI. Thank you, you mentioned something that I don't know if you were in the room when I was questioning Mr. Wilson, but I asked him with respect to the current process, did he believe that you would have—the current process would force fewer suppliers ultimately, sooner but certainly later, fewer suppliers in the business and then ultimately, we would have more beneficiaries? Everyone knows that we are going to have more beneficiaries, fewer suppliers. Would that lead to increased costs ultimately? He said no. Can you comment further on that based upon what you already said?

Mr. SALE. Well, I am not.

Mr. TIBERI. Why you believe that there will be fewer suppliers under the current system?

Mr. SALE. Several reasons. First of all, this program as it is designed, has been in play a year. And already, 40 percent of those who submitted bids that are in bid areas that didn't get them, 40 percent of those businesses are going out of business.

I have brought letters with me from people in CBAs. One company in particular that was almost 30 years old, they were left out

of the Medicare system. And when their patients were moved over, they went out of business. And it is not unusual to see those businesses fall in the process that is happening now.

As the prices go down and the incentives to improve service and access are decreased, I believe service and access will decrease. And as businesses go out of business, and the 3-year contracts run on, when the rebid comes, there will be fewer and fewer people to bid, and subsequently, bids will go up. It is a supply/demand axiom that is pure, is true in every area.

Mr. TIBERI. Thank you, Mr. Chairman, for indulging me and allowing me to go over. If I can just ask the chairman if we could ask both the—Mr. Sale's association, and Mr. Marx's association to provide some additional information regarding the number of folks who have gone out of business, because that is in direct conflict to what Mr. Wilson said.

Chairman HERGER. Without objection, if you would supply the committee with that information, we would appreciate it. Certainly.

Mr. SALE. Yes, sir.

Chairman HERGER. Thank you. Mr. Stark is recognized.

Mr. STARK. Thank you, Mr. Chairman, and I thank the panel for their informative testimony. My concern is that outside of the fact that I get more emails from the Scooter Store than I do from Viagra telling me that I can have the scooter free, and Medicare will pay for it, the small supplier who doesn't bid is pretty much put out of business by the person who wins the bid. I don't see that that is particularly fair.

I guess, to cut to the chase, I would suggest, and I would ask Mr. Chiplin if there would be any real problem? We do it in most other things that we just set through negotiation or comparative shopping, set a price. This is what we will pay for oxygen. I don't know that I would want to pay any more than a welding shop does, but the same guy delivers the oxygen to the welding shop as to grandma. I see absolutely no difference there.

It has to be there at a certain time. They don't want to let them run out. A tank is a tank. They are all standard. There are only a couple of suppliers of oxygen tanks. They are all alike. And I presume they are all priced the same. Perhaps they are made in different parts of the country for shipping reasons, so why wouldn't it be possible for the government to set a price? And then anybody who chooses to provide the equipment or the service can do it?

Mr. CHIPLIN. Well, thank you, Mr. Stark. In general, there are many ways that you could have designed the program, and achieved the similar kind of goal. I think what you have recommended should be explored. The bottom line for the beneficiary community is that they are able to get the services that they need, timely, and in the sufficient amount and quality.

Mr. STARK. All of these products, it seems to me, are something I could go to the medical supply store and buy.

Mr. CHIPLIN. Yes, sir.

Mr. STARK. And so why should a Medicare beneficiary, or myself, or anybody else have anything different? If we go out and the government goes out to buy a pickup truck, we set a price. And then if you want to deal, if you are a local agency with a local Ford dealer, Chevy dealer go ahead, wherever you happen to like the

service. Same thing is true of Star Wars or nuclear weapons. We don't have to put those out to bid. We don't have a lot of suppliers for them, but——

Mr. CHIPLIN. It I think what you are——

Mr. STARK. [continuing]. But what we have in particularly small suppliers, who are apt to, you know, the Scooter Store guys go around and get the bid in the community, and then they subcontract through the local person and skim off the top. I don't know why we should have to continue that. Is there any good reason?

Mr. CHIPLIN. Not to my knowledge, sir.

Mr. STARK. Anybody else think of any reason why we shouldn't just set a price, and if you want to sell at the price, fine.

Mr. SALE. My I respond?

Mr. STARK. Sure.

Mr. SALE. Thank you for the question, Congressman Stark. I hear intermittently as we are talking about the services that Medicare offers under the DME benefit, and I would like to clear up, there are no services paid for under the DME benefit. It is only equipment, one. Two, when we are paid, we are only paid for the equipment, but the list of things that we must do in order to get paid continues to grow through the years as CMS has added requirement after requirement after requirement.

Mr. STARK. You buy a jet fighter, you are paying for the jet and not all of the fussing, so——

Mr. SALE. That is true. You pay for the jet and the building and the labor that goes into it. You don't pay anything for—you have an oxygen machine delivered, they don't pay anything for the on-call, the 24/7 on-call. They don't pay anything for the billing requirements.

Mr. STARK. Why should they? That is part of the service, for heaven's sakes. I mean, come on.

Mr. SALE. They don't pay for service.

Mr. STARK. McDonald's is there 24/7. I don't pay any more for the hamburger at midnight than I do at noon.

Mr. SALE. We are an emergency service, and the calculations that they have put in place for reimbursing oxygen, and CPAPs, are based only on the cost of the equipment.

Mr. STARK. Fine.

Mr. SALE. They don't include the service. We have to put that in, that is the small business' investment in its community and in the patient care.

Mr. STARK. Right. And why should anybody be excluded?

Mr. SALE. Well, we have to supply that, otherwise you could go to an Internet and get what you wanted.

Mr. STARK. That is even better.

Mr. SALE. But they can't bill Medicare. They don't meet the requirements that are——

Mr. STARK. If it is at a price, I mean, all of this mumbo jumbo about bidding is nonsense. Government could set a price, and anybody that could provide it would. That is how it should work.

Mr. SALE. And I think that is the way it was. They were administratively set for years, and then Congress came up with the idea to see if we could drive the cost down a little bit through competition. And competition is fine. We don't mind competition. We just

want fair competition, and if you are going to have a bidding process, we would like to have competition as one of the factors of it.

Mr. STARK. I say, let's do away with the bidding process. Set a price.

Mr. SALE. Really, we should do away with the CMS process that is cumbersome and time-consuming and takes years and years and years; put an MPP plan in place that could be done in 6 months, and rebid it every 2 years so that we can be sustainable for decades to come.

Mr. STARK. Well, we are not here in the business to sustain your business for decades to come. That is hardly competitive.

Mr. SALE. No, I have 78 million baby-boomers coming and aging is a disabling process.

Mr. STARK. I don't care.

Mr. SALE. We are planning for that.

Mr. STARK. Okay. Thank you, Mr. Chairman.

Chairman HERGER. Thank you, and it would be nice if we could set a price. Maybe set it a little bit above free, but how do we know what that price is? I think that is what the question is. How do we know what the price is, and I think the success of this great Nation of ours is the free enterprise system where the marketplace has set what that price is. And I think that is what really the purpose of our hearing is today, to how do we get the lowest price that we can have and still sustain the quality that we need.

With that, I want to thank each of our witnesses for your testimony today. Hearing such a range of perspectives has been helpful to the subcommittee. It is important for members to understand the impact that competitive bidding has on beneficiaries, suppliers, and Medicare expenditures. Since it would not be prudent, or viable to simply return to the often, excessive payment rates of the old DME fee schedule, I want to commend the supplier industry for offering an alternative that is based on competition and aims to set prices using market forces.

The subcommittee will carefully consider all of this information. It is my hope that the Congressional Budget Office will soon inform us as to the spending implications of moving to such a proposal. As a reminder, any member wishing to submit a question for the record will have 14 days to do so. If any questions are submitted, I ask that the witnesses respond in a timely manner. With that, the subcommittee is adjourned.

[Whereupon, at 11:32 a.m., the subcommittee was adjourned.]

Questions For The Record
Member Questions

Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012

Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services

Chairman Herger

Question: **One of the criticisms raised by suppliers during the initial Round 1 was that a 26 percent reduction in reimbursements wouldn't be sustainable. However, when suppliers rebid Round 1, the median winning bids were even lower, representing between 32 and 35 savings, on average. Can you explain why the rebid produced greater savings? Does CMS expect this trend to continue in Round 2?**

Answer: CMS has not specifically investigated why the Round 1 Rebid resulted in greater savings than the initial Round 1 and has not yet completed bid evaluation for Round 2. However, the Department of Health and Human Services' Office of Inspector General, the Government Accountability Office, and other independent analysts have repeatedly warned[1] 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. The competitive bidding program single payment amounts are based on suppliers' bids that have been carefully screened and evaluated to ensure that they are bona fide (rational and feasible). CMS' real-time claims monitoring program and subsequent follow-up have shown that beneficiaries' access to necessary and appropriate items and supplies has been preserved. This would indicate that the payment amounts established through the competition are sustainable.

Question: **A concern frequently expressed is that winning suppliers may sign a contract with CMS with the expectation that it fulfill a certain amount of capacity within a market only sit on its hands and not supply the product. How many of the 356 suppliers have failed to supply even a single item? Has CMS tracked the expected market share identified in suppliers' bids against actual market share in the Round 1 re-bid?**

Answer: The capacity estimates in a supplier's bid represent the maximum number of items the supplier estimates it could furnish annually throughout a competitive

[1] **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.**

bidding area (CBA) if awarded a contract. CMS validates these capacity estimates during the bid evaluation process and awards contracts to more than enough suppliers to meet beneficiary demand. The competitive bidding program contracts require each contract supplier to furnish items in its contract to any beneficiary who lives in or visits the competitive bidding area and requests those items from the contract supplier. Because of statutory requirements that guarantee beneficiary choice, beneficiaries may choose to obtain their items from any contract supplier. Therefore, competitive bidding program contracts do not guarantee any set volume of business, and contract suppliers must compete based on customer service and quality to gain market share. Thus, a contract supplier that furnishes items in its contract to any beneficiary who lives in or visits the CBA who requests them is in compliance with competitive bidding program rules even if that supplier has not furnished the maximum number of items in its bid. Contract suppliers can also furnish more than the maximum number of items in their bids. It is important to stress that CMS' real-time claims monitoring and subsequent follow up has indicated that beneficiaries' access to necessary and appropriate items and supplies has been preserved.

Twelve contract suppliers that have contracts only for the group 2 complex rehabilitative power wheelchair product category did not furnish any items in their contracts during 2011. CMS was required by law to bid this product category in the Round 1 Rebid, but the vast majority of beneficiaries who need complex rehabilitative power wheelchairs use group 3 or higher power wheelchairs, not group 2. Because of very low demand and low savings potential for these items, this product category was not included in the current Round 2 competition.

Thirteen suppliers that have contracts for other product categories did not furnish any items in their contracts during 2011. This is less than 4 percent of the 356 contract suppliers. CMS recently conducted secret shopping for these 13 suppliers and confirmed that most of them are prepared to meet their contractual obligations. CMS will take enforcement action against any supplier that is determined to be in breach of its contract.

We note that CMS has terminated the contracts of a few suppliers; some of these suppliers may not have furnished contract items before termination.

Question: **I understand that many in the supplier industry are touting an analysis of claims information for the first nine months of 2011 showing beneficiary access problems and adverse outcomes. How do you respond to criticisms that this data analysis contradicts CMS' assertion that the program isn't harming beneficiaries?**

Answer: CMS is aware of a January 20, 2012 paper that claims to have found evidence of beneficiary access problems in the Round 1 Rebid competitive bidding areas. The paper contains strikingly inaccurate results because it uses technically flawed

analysis; the actual results described in CMS and GAO testimony are significantly different. Here are examples of some of the deficiencies that caused the inaccurate conclusions in the paper:

- It assumes that the pre-competitive bidding market is optimal and should be preserved when in reality there have been numerous reports documenting problems with fraud and overutilization in the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) sector.
- It improperly analyzes claims data by:
    - failing to consider claims lag (the widespread practice of waiting to submit claims for a period of time (up to 12 months) after items are furnished) and thereby greatly underestimating the number of items furnished since the program began;
    - counting claim lines (which can each include a varying number of items) instead of allowed services;
    - failing to make any adjustments to consider typical DMEPOS billing patterns (i.e., more claims toward the end of the year after beneficiaries have met their deductible); and
    - using date of claims receipt to establish baseline utilization but switching to date of service for 2011 (not comparing "apples to apples").

  Together, these mistakes resulted in extremely inaccurate volume estimates.
- It misrepresents the health status outcomes data that is available on the CMS website in the following ways:
    - It looks only at data from competitive bidding areas and ignores comparator areas.
    - It does not examine historical trends where the CMS data track trends for four years.
    - It relies on incorrect assumptions about the equipment needs of beneficiaries being tracked in the monitoring data. Specifically, it incorrectly assumes that all people with a diagnosis that makes it likely that they may need competitively bid equipment actually do need the equipment. It also assumes that anyone who has not submitted a claim for the equipment is still in need of the equipment (beneficiaries may have received equipment unnecessarily or have been victims of fraud). Further, it assumes that beneficiaries who have not submitted a claim for an item are not using the item, but data show that beneficiaries had months of oversupply of certain items[2]. It builds on these mistakes by

[2] CMS's monitoring revealed declines in the use of mail-order diabetes test strips and continuous positive airway pressure (CPAP) supplies in the competitive bidding areas. In response to these declines, CMS initiated three rounds of calls to users of these supplies in the nine competitive areas, 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

assuming that any negative health outcomes for beneficiaries who are not using the equipment result from lack of use.

In fact, the health status outcomes data, which are posted on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html, have consistently shown that the trends in competitive bidding areas are consistent with trends in comparison areas. No changes in health status outcomes resulting from the competitive bidding program have been observed to date.

Question: **What factors went into CMS' decision to select the nine geographic areas that would first be subjected to competitive bidding? Do you think the prior spending levels in these areas may have had something to do with the decreased utilization in these MSAs once competitive bidding was implemented?**

Answer: The statute originally required that competition under the program begin in 10 of the largest Metropolitan Statistical Areas (MSAs) in 2007. The competitive bidding program regulations required a formula-driven methodology for selecting these MSAs. From the MSAs with the largest total populations, we identified the MSAs with the highest Medicare allowed charges for DMEPOS items. We scored these MSAs using criteria that equally weighed the allowed charges per beneficiary and the number of suppliers per beneficiary for an area. In selecting the MSAs for 2007, we excluded the largest MSA areas based on population (New York City, NY; Los Angeles, CA; Chicago, IL) to allow us to gain more experience with competitive bidding programs before we included these areas. We also excluded MSA areas that span more than one of the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The Medicare Improvements for Patients and Providers Act of 2008 required the Round 1 Rebid competition to occur in the same areas as the original Round 1 except for San Juan, Puerto Rico.

The nine competitive bidding areas were among the most fraud-prone areas, with aberrant claims volume prior to selection of the competitive bidding areas as shown in the following table:

Comparison of Allowed Charges in
Competitive Bidding Areas vs. Non Competitive Bidding Areas (2005)

MSA	FFS Pop	Allowed Charges	$/bene
Miami*	517,370	$221,660,443	$428.44
Dallas*	470,562	$139,910,862	$297.33

multiple months' worth, and therefore did not need to obtain additional supplies when the program began. This would suggest that beneficiaries received excessive replacement supplies before they became medically necessary. CMS concludes that the competitive bidding program may have curbed inappropriate distribution of these supplies that was occurring prior to implementation.

Riverside*	239,486	$52,910,209	$220.93
Chicago	1,085,254	$173,922,952	$160.26
Philadelphia	639,753	$97,487,063	$152.38
San Francisco	357,207	$45,565,320	$127.56

*Competitive Bidding Area

We believe that the implementation of the competitive bidding program has curbed inappropriate distribution of certain competitively bid items and that it helps prevent fraud and abuse.

Question: **The agency indicates that beneficiaries continue to have access to needed products under competitive bidding and that they are not experiencing adverse health outcomes. Understanding how beneficiaries feel about their experience is also an important consideration. Can you describe what CMS has found in its effort to assess beneficiary satisfaction?**

Answer: CMS conducted beneficiary satisfaction surveys in the Round 1 Rebid areas and comparison areas. The survey collected beneficiary satisfaction ratings for six issues: the beneficiary's initial interaction with the supplier, the training received regarding the item, the delivery of the item, the quality of the item provided by the supplier, the customer service provided by the supplier, and the supplier's overall complaint handling. Based on the survey results, the vast majority of beneficiaries (over 85 percent) in both competitive bidding areas and comparison areas are pleased with the quality of items and services. There were minor fluctuations in survey results in both competitive bidding areas and comparison areas before and after January 1, 2011, but we do not believe these are significant.

In its review of the beneficiary survey results, the GAO confirmed CMS' finding that the survey did not show issues with beneficiary satisfaction. Here are the GAO's findings[3]:

> CMS's beneficiary satisfaction survey did not reveal systemic beneficiary access or satisfaction problems with CBP. For all six questions in the competitive bidding areas, approximately 67 percent of beneficiaries reported their services as being "very good". Beneficiaries in competitive bidding areas rated as "good" or "very good" their initial interaction with the DME supplier (89 percent), the training received (86 percent), delivery (91 percent), quality (90 percent), customer service (88 percent), and complaint handling (84 percent). Results within competitive bidding areas show a drop of one to three percentage points on each of the six questions from pre-implementation to post-implementation. Beneficiaries in the

[3] *Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid*, GAO-12-693

comparison markets rated their experiences similarly to those in competitive bidding markets: these beneficiaries rated as "good" or "very good" their initial interaction with the DME supplier (93 percent), the training received (89 percent), delivery (93 percent), quality (93 percent), customer service (91 percent), and complaint handling (88 percent).

Question: **The supplier industry is advocating for a "clearing price" reimbursement instead of the current "median bid price" structure. It seems to me that CMS has the authority to make this change. Has CMS considered such an approach and, if so, what did it conclude?**

Answer: It is very important to stress that the competitive bidding program has been carefully designed and balanced to ensure a sustainable program that achieves savings and preserves beneficiary access and choice. For example, the program's method for estimating beneficiary demand results in a generous "cushion" of excess supplier capacity. The generous demand results in the selection of a larger number of winning suppliers than if demand were set more conservatively. In turn, the number of winning suppliers has a direct impact on the calculation of the single payment amounts. Any change to the pricing methodology would require reconsideration of the demand estimation methodology and other interconnected policies.

The competitive bidding program conducts bidding by product category rather than by individual item. CMS adopted this approach for many reasons, including beneficiary convenience and supplier business viability. Although bidding is by product category, the statute requires a single payment amount for each item based on bids submitted and accepted for that item. CMS uses a composite bid (the sum of a supplier's weighted bids within a product category) for purposes of determining the winning suppliers and then determines the price for each item using the median bid of the winners. The bidder with the "market clearing" composite bid may have high or low bids for individual items.

CMS considered the use of the maximum winning bid to set the price for each item during notice and comment rulemaking. We were concerned about using the maximum bid for each item because this approach would have led to program payment amounts that were higher than necessary. In contrast, use of the median takes into consideration all bids submitted and accepted and not just the highest and lowest bids. The median is not influenced by outliers at the extremes of a data set. For this reason, the median is often used when there are a few extreme values that could distort what might be considered typical.
We recognized the need to ensure that all bids are rational and feasible, so we screen and evaluate all bids to make sure they are bona fide. If necessary, CMS requires bidders to submit supporting documentation (e.g., invoices and rationales) to prove that they can furnish items with very low bid amounts. Any

bids that are not bona fide are disqualified and are not used in the single payment amount calculations. We believe the median of the accepted bids represents a reasonable payment amount that does not favor large or small suppliers.

We note that 92 percent of suppliers offered contracts in the Round 1 Rebid accepted the contracts, and CMS had no difficulty in executing contracts with enough contract suppliers to meet beneficiary demand.

Question: **CMS combined very different types of equipment into a single General Home Equipment product category in the Round 1 Recompete. This appears contrary to CMS regulations that say a product category will include related items used to treat similar medical conditions.**

In the General Home Equipment category, TENS equipment and supplies are the only products that treat pain. The way the category is configured, however, a TENS manufacturer cannot bid to supply TENS equipment unless it also provides more than 60 other products that have nothing to do with pain care.

Why did CMS make this change? Will CMS work with stakeholders to rework the proposed product categories to separate distinct products treating different medical conditions into separate product categories?

Answer: CMS meets frequently with stakeholders interested in the competitive bidding program to understand their concerns and perspectives. CMS selected the Round 1 Recompete product categories after consideration of feedback from suppliers and referral agents and analysis of our statutory mandate to phase in bidding for additional DMEPOS items. We believe these product categories will be beneficial for suppliers and beneficiaries. Some suppliers in the Round 1 Rebid expressed concerns about winning in one product category and not another. Including several related products in one product category addresses this concern for suppliers. Larger, more consolidated product categories will promote one-stop shopping for beneficiaries, simplify the referral process and enhance the opportunities for winning suppliers. Furthermore, we note that CMS is required to continue to phase in bidding for DMEPOS items that are subject to competitive bidding. We believe that phasing in numerous, separate product categories for lower volume items would make the program overly complicated and could lead to non-viable competitions, particularly in smaller competitive bidding areas. Certain stakeholders have contacted CMS to express concern about some of the Round 1 Recompete product categories. CMS met with these stakeholders and is looking into their concerns.

Question: **What is the status of the CMS effort to collect and make available information on the products, brands, and quantity of items that contract suppliers provide to beneficiaries in the competitive bidding areas? My understanding is that CMS requires contract suppliers to submit this "Form**

C" data quarterly and that it was to be used by beneficiaries, Medicare customer service representatives, and referral sources to help patients get needed DME.

Answer: All contract suppliers must update the brands that they are providing on a quarterly basis on a report called "Form C." This information is being collected to assist beneficiaries, Medicare customer services representatives, and referral agents and is available on the supplier locator tool at www.medicare.gov/supplier or by calling 1-800-MEDICARE [(800) 633-4227].

We note that Form C also originally collected the approximate number of each brand of competitively bid item furnished to beneficiaries during the previous quarter. This information was intended to help CMS monitor the program. However, after analysis of the first two quarterly submissions and reviewing contract supplier feedback, CMS determined that the information could not be used to monitor the program and was very burdensome for contract suppliers. More importantly, CMS implemented a comprehensive monitoring system, including real-time claims analysis which effectively measures beneficiary health status outcomes and access.

Question: **It seems to me that it would be more equitable if CMS could calculate the median single price payment amount by using only the bids of the contractors who actually end up signing a contract. This would require the agency to adjust the announced single price after all of the contracts were signed, but it seems feasible. What does the agency think about this approach?**

Answer: CMS carefully screens and evaluates bids to ensure that they are bona fide (rational and feasible) before determining the single payment amounts and offering contracts. Since only bona fide bids from qualified suppliers are included in the array of bids used to set prices, recalculating payment amounts based on contract rejections would not improve the validity of the single payment amounts. Additionally, 92 percent of suppliers that were offered contracts accepted those contracts. CMS analyzed the bid amounts for the most commonly used items in each product category from suppliers that chose not to accept any contract and found that approximately the same number of bids were above and below the single payment amounts. Such results indicate the single payment amounts are set at an appropriate level based on the bids received during the Round 1 Rebid.

CMS also has some concerns about the administrative feasibility of this reverse-contracting approach because it could require multiple iterative rounds of contract negotiations. We also note that suppliers may be unwilling to accept new contract offers if the prices go down as a result of an adjustment.

Question: **CMS has stated that it adjusts the market capacity in supplier bids. What are the circumstances in which the agency makes such adjustments and does the agency use consistent guidelines in making these determinations?**

Answer: CMS has issued a fact sheet that explains the process for review of supplier capacity and expansion plans. The fact sheet is available on the Competitive Bidding Implementation Contractor website at the following link: http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf/$File/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf.

Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012

Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services

Mr. Price

The release of additional information regarding Round 1 of the DME competitive bidding program is necessary in order for Congress to fully evaluate this program and assess the validity of the structural concerns raised by so many experts. CMS should provide the House Ways and Means Health Subcommittee with the following information:

1. **Provide the charts with the data appended that track the utilization for each DME competitive bidding product category, from 2008 to present, for each Competitive Bid Area (CBA) and its comparator city. Provide a full set of charts as follows for each product category:**
   - **A. Percent of the Access Group (e.g. Cardio-Pulmonary Narrow, Diabetic, Sleep Disorders, a set for each one) purchasing or renting (the product category, such as Oxygen, Mail Order Diabetes Supplies, CPAP, etc.);**
   - **B. Percent of the Medicare A/B fee for service (FFS) population purchasing or renting (a set for each product category); and**
   - **C. A set of graphs for each of the above that reflects, in total, all CBAs and comparator cities combined.**

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html. These charts are based on 100 percent of Medicare claims and provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened. The health status health outcomes being monitored include events such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. As shown in the charts, fluctuations in outcomes match closely in competitive bidding areas and

comparison areas both before and after the start of the competitive bidding program. Historic seasonal trends also continue to be reflected. There have been no changes in beneficiary health status outcomes resulting from the competitive bidding program observed to date.

Comparing trends in claims utilization data alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of claims does not necessarily provide a reliable measure of the number of medically necessary items furnished to Medicare beneficiaries. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. The results of CMS's real-time claims monitoring is also supported by the low number of beneficiary complaints the agency has received. For these reasons, we strongly believe that the best way to evaluate the program is to use the charts that are on the CMS website. We would be pleased to provide Members with a briefing to go over the health status outcomes in more detail and to explain the real time claims monitoring program methodology.

2. Provide, by product category and for each CBA and each comparator city, the number of unique Medicare Beneficiaries with a claim submitted, and, separately, a claim paid, for the following two time periods:
   A. Date of Service from October 1 through December 31, 2010
   B. Date of Service from October 1 through December 31, 2011

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html. These charts are based on 100 percent of Medicare claims and provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened. The health status health outcomes being monitored include events such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. As shown in the charts, fluctuations in outcomes match closely in competitive bidding areas and comparison areas both before and after the start of the competitive bidding program. Historic seasonal trends also continue to be reflected. There have been no changes in beneficiary health status outcomes resulting from the competitive bidding program observed to date.

Comparing trends in the number of beneficiaries for whom claims were submitted or paid alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of beneficiaries for whom claims were submitted or paid does not necessarily provide a reliable measure of the number of Medicare beneficiaries who need or receive these items. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. These targeted outreach efforts reflect the Agency's commitment to act on the health status outcomes information produced from our comprehensive claims monitoring system. This information is displayed in the charts available on the CMS website. We would be pleased to provide Members with a briefing to go over these health status outcomes in more detail and to explain the real time claims monitoring program methodology.

3. Provide for each product category in Rebid areas the number of unique DMEPOS suppliers that submitted a claim for a date of service in December 2010 and, separately, in December 2011 as follows:

A. Number of Contracted suppliers in each CBA submitting a claim;

B. Number of non-contracted suppliers in each CBA submitting a claim; and
C. For each comparator city, the number of suppliers submitting a claim.

Answer: The attached Excel document shows the number of unique DMEPOS suppliers with any allowed charges for competitively bid items in 2010 and 2011 in CBAs and comparator areas. We note that many of these suppliers had very small allowed charges. To help provide perspective about suppliers with a more meaningful presence in the area, we have also provided the number of unique DMEPOS suppliers with allowed charges for competitively bid items of at least $10,000 in these years.

4. **Provide for the product categories of oxygen, CPAP and enteral nutrition, charts that track the health outcomes (https://www.cms.gov/DMEPOSCompetitiveBid/01A3_Monitoring.asp) of beneficiaries in each CBA and comparator city who:**
   A. Had a claim for the product category with a date of service between October 1, 2010 and January 31, 2011, and
   B. Did NOT have a claim for the product category with a date of service between October 1, 2011 and January 31, 2012, and
   C. Are not deceased.

Answer: CMS does not currently compile claims data in the manner requested. CMS understands the Subcommittee's interest in assessing the health status of beneficiaries with a history of equipment use who no longer use the product. We note that it is difficult to measure "non-use" with Medicare claims data. Instead, we identify individuals that are not *billing* for a particular product. These people may have excess replacement supplies, may have reached the end of their billing period, or may no longer need the product. It is possible that these beneficiaries may have changes in health status over time. However, these changes could occur for many reasons which may not be related to competitive bidding. This will make the results of this analysis difficult to interpret. We have summarized two hypothetical examples below.

Example 1: A beneficiary receives a CPAP device in 2010. Over the next few months, the person's health status improves and the CPAP device is no longer necessary. The beneficiary does not have a CPAP-related claim in 2011-2012. Since the beneficiary's health status has improved, he has decreased rates of emergency department utilization and fewer physician visits in 2011 compared to 2010. We cannot conclude that the beneficiary's improved health status outcomes are the result of the competitive bidding program.

Example 2: In 2010, a beneficiary is in her 36th month of a rental period for a portable oxygen concentrator. Since Medicare pays for oxygen using a 36 month capped rental, the beneficiary does not have an oxygen-related claim between October 1, 2011 and January 31, 2012, even though she is continuing to receive oxygen. The beneficiary has severe COPD along with several other conditions, and her health status is deteriorating with age. The beneficiary visits the hospital

more often in 2011 than 2010 as a result of her worsening health status; however, we cannot use claims data to conclude that this is related to competitive bidding.

CMS agrees that it is very important to monitor access and outcomes for all beneficiaries who are likely to need a competitively bid item based on their medical needs, including beneficiaries who do not have a claim for the item. The CMS real-time claims analysis program is currently tracking this information; the relevant information can be found on the "Access Group" charts in the health status outcomes charts on the CMS website (see: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html). The "Access Group" tracking has been designed to control for non-competitive bidding program effects and provide an accurate picture of program results.

Despite the difficulty in measuring the "non-use" of a product, we have estimated the cost of compiling the requested data to be approximately $20,000 to $40,000. The compilation would take at least several weeks.

To follow up on the May 9 House Ways and Means Health Subcommittee hearing on the DME competitive bidding program and alternative bid program support by the DME sector, CMS should answer the following questions –

Question: **Can you give examples of other government agencies that do not require binding bids for auctions and/or use the median bid price to set reimbursement?**

Answer: The DMEPOS Competitive Bidding Program is not an auction program. It is a competition-based methodology for determining Medicare payment amounts for equipment and services furnished to beneficiaries in their homes. CMS is unaware of any other government program that uses a competitive bidding program structure similar to the one mandated by section 1847 of the Social Security Act. There are unique statutory requirements for the program that make it very different from procurement auctions. For example, the Medicare statute does not provide any authority that would permit CMS to require winning suppliers to accept contracts. Further, the statute requires the selection of multiple contract suppliers even if only one supplier could satisfy beneficiary demand on its own. Also, because of statutory requirements that guarantee beneficiary choice, beneficiaries may choose to obtain their items from any contract supplier. Therefore, competitive bidding program contract suppliers are not guaranteed to receive any Medicare business.

We note that the competitive bidding program has been designed to conduct bidding by product category rather than by individual item. CMS adopted this approach for many reasons, including beneficiary convenience and supplier business viability. Although bidding is by product category, the statute requires a single payment amount for each item based on bids submitted and accepted for that item. CMS uses a composite bid (the sum of a supplier's weighted bids

within a product category) for purposes of determining the winning suppliers and then determines the price for each item using the median bid of the winners. Setting the single payment amount for each item at the median of accepted bids for that item ensures that all accepted bids are reflected and protects against outlier bids for particular items.

Question: **Does CMS support the use of binding bids for the competitive bidding program? If CMS believes it lacks statutory authority to require binding bids, would the agency support legislation to address this issue?**

Answer: The Medicare statute does not provide any authority that would permit CMS to require winning suppliers to accept contracts. This is consistent with other provisions of the Medicare statute that make supplier participation in Medicare voluntary. Although the law does not provide any authority for requiring suppliers to accept contracts, it is not clear that such authority is needed. In the Round 1 Rebid, 92 percent of suppliers that were offered contracts accepted those contracts. There have been no indication of any beneficiary access problems, and CMS has not had to add any new suppliers to meet demand.

Question: **CMS has claimed that there have only been 151 complaints, but 127,466 inquiries from Medicare beneficiaries regarding Round 1 of competitive bidding. Can CMS explain what constitutes a complaint versus an inquiry? Can CMS give details how it addressed the complaints and inquires?**

Answer: Complaints are inquiries that express dissatisfaction and cannot be resolved by a 1-800-MEDICARE call center operator. The vast majority of inquiries were about routine matters, such as questions about the program or finding a contract supplier. All complaints were assigned to program experts for prompt resolution. Most of the issues that were elevated involved providing assistance in finding a contract supplier (particularly mail order diabetic supplies contract suppliers) or finding a supplier to perform a repair of beneficiary-owned equipment (particularly a repair of a power wheelchair). We note that repairs are not a competitively bid service, but we are tracking repair issues in competitive bidding areas. We also note that we modified[4] our educational fact sheet on repairs of beneficiary-owned equipment in response to the complaints; the number of complaints about repairs went down dramatically after the issuance of the revised fact sheet.

Question: **CMS planned to collect the type of products that were being provided to Medicare beneficiaries in bid areas using something called Form C. Regardless of the reason CMS canceled the collection of this information, how is CMS ensuring that beneficiaries get high quality DME when the average price decreased by 32 percent?**

[4] CMS clarified the distinction between repairs, which can be performed by any enrolled suppliers, and replacements, which can only be furnished by contract suppliers.

Answer: The competitive bidding program has been designed to ensure that beneficiaries have continued access to quality items that meet their needs. Contract suppliers are required to meet quality standards, be licensed and be accredited by an approved independent accrediting organization. As a term of the contract, suppliers must make available the same range of products to beneficiaries that they make available to non-Medicare customers.

A quality item is an item that meets applicable Food and Drug Administration regulations and medical device effectiveness and safety standards and that meets the needs of the beneficiary receiving that item. CMS believes beneficiaries are receiving quality items under the competitive bidding program because we have received few inquiries and complaints about the program and because our real-time monitoring shows that there have been no significant changes in beneficiary health status outcomes resulting from the competitive bidding program.

Question: **In Round 2, CMS included power and manual wheelchairs in one very large product category, this seems to discriminate against smaller providers who are less likely to provide all items in this very large product category. Can CMS explain the rationale for such large product categories and how even larger bid categories in the Round 1 recompete process may negatively impact small DME providers and patients? Did you seek input from the DME sector or Program Advisory and Oversight Committee (PAOC) on these broad Round 1 recompete categories?**

Answer: CMS meets frequently with stakeholders interested in the competitive bidding program to understand their concerns and perspectives. CMS selected the Round 1 Recompete product categories after consideration of feedback from suppliers and referral agents and analysis of our statutory mandate to phase in bidding for additional DMEPOS items. We believe these product categories will be beneficial for suppliers and beneficiaries. Some suppliers in the Round 1 Rebid expressed concerns about winning in one product category and not another. Including several related products in one product category addresses this concern for suppliers. Larger, more consolidated product categories will promote one-stop shopping for beneficiaries, simplify the referral process and enhance the opportunities for winning suppliers. Furthermore, we note that CMS is required to continue to phase in bidding for DMEPOS items that are subject to competitive bidding. We believe that phasing in numerous, separate product categories for lower volume items would make the program overly complicated and could lead to non-viable competitions, particularly in smaller competitive bidding areas. Certain stakeholders have contacted CMS to express concern about some of the Round 1 Recompete product categories. CMS met with these stakeholders and is looking into their concerns.

Question: **Recently, there were a number of indictments in Miami, Florida related to Medicare fraud, where several individuals had prior criminal/felony records. Can CMS explain how these individuals received Medicare billing numbers?**

Answer: CMS has the authority to deny or revoke Medicare billing privileges for certain felony offenses. Examples of felony convictions that may lead to denial or revocation in Medicare include felony crimes against persons, financial crimes, or felonies that have placed Medicare beneficiaries at immediate risk. Not all felony convictions result in revocation of Medicare billing privileges.

In addition, the Department of Health and Human Services Office of Inspector General (OIG) also excludes individuals and entities from Medicare, Medicaid, and the Children's Health Insurance Program based on felony or misdemeanor convictions related to the Medicare or Medicaid programs or related to the abuse or neglect of patients. When the OIG excludes an individual, CMS revokes the billing privileges for the same individual.

Without the names of specific individuals, it is difficult for CMS to determine whether their particular prior felony convictions would require a revocation of Medicare billing privileges. We are happy to provide additional information if the Committee would provide the names of the specific individuals referenced in the question.

Question: **In the testimony you stated that "Small suppliers do not account for that much of the market now so to meet this requirement, beneficiaries would have to be assigned to small suppliers, under CMS' current bid program, beneficiaries choose suppliers." Can you please advise us what percent of the total supplier number fall in the less than $3.5 million category? Additionally, what percent of total suppliers fall in the less than $10 million category?**

Answer: First, please note that Mr. Wilson's testimony referred to the percent of beneficiary demand met by small suppliers, not the number of small suppliers. Also, the small supplier definition (a supplier that generates gross revenue of $3.5 million or less in annual receipts from Medicare and non-Medicare revenue) applies only to the competitive bidding program. CMS does not collect supplier gross receipt data outside of the competitive bidding program, so we are unable to provide the requested data. However, in the Round 1 Rebid small suppliers make up about 51 percent of the contract suppliers. In 2011, small suppliers furnished 13.88 percent of the market share for competitively bid items.

Question: **CMS has "grandfathered" most product categories subject to the competitive bidding program. However, the one product in competitive bidding that is provided in nursing facilities, enteral nutrition, was not grandfathered. As a result, wherever competitive bidding has been instituted or will be in the future, all enteral nutrition patients lose their enteral**

suppliers if they are not bid winners. Grandfathering was promoted by CMS as a means to ensure that patients do not fall through the cracks, but that safeguard simply does not exist for enteral patients who are residing in nursing facilities.
Will CMS explain why it decided not to grandfathered enteral nutrition patients in the competitive bidding program? Will CMS extend this protection in the future expansions of the program? If not, will the agency explain why?

Answer: The statute does not give CMS the authority to grandfather enteral nutrition. Section 1847(a)(4) of the Social Security Act requires CMS to establish a process by which rental agreements for durable medical equipment (DME) and supply arrangements for suppliers of oxygen and oxygen equipment entered into before the implementation of a competitive bidding program may be continued. This statutory authority does not apply to other DMEPOS, such as enteral nutrition, equipment, and supplies that are covered under the prosthetic device benefit and not the DME benefit.

Question: **How many suppliers who billed Medicare in the Round 1 CBAs in last quarter of calendar 2010 were also billing Medicare in the last calendar quarter of 2011?**

Answer: The following tables show the number of suppliers that furnished durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items in the Round 1 Rebid competitive bidding areas and comparator areas annually and per month in 2010 and 2011. We have not analyzed these numbers to determine the reasons for the change in the number of suppliers but note that the percent change in the number of suppliers in Table 1 is similar in competitive bidding areas and comparators. This would indicate that forces beyond competitive bidding played a role in the change.

Table 1: Yearly Supplier Summary, 2010-2011
Suppliers by 10-digit Provider Transaction Access Number

Year	CBAs						Comparator			
	Number of Suppliers	Number of Suppliers within Allowable Charge Range*					Number of Suppliers	Number of Suppliers w Ran		
		< $10,000	$10,000 - $50,000	$50,000 - $100,000	$100,000 - $500,000	$500,000 +		< $10,000	$10,000 - $50,000	$50,0 - $100,(
2010	23,059	17,890	3,083	1,060	607	419	19,994	15,689	2,613	798
2011	22,703	17,879	3,038	906	543	337	19,758	15,462	2,635	819

* Allowable charge ranges exclude the upper bound

Table 2: Monthly Supplier Summary, 2010-2011[5]
Suppliers by 10-digit Provider Transaction Access Number

Month	CBAs						Comparat		
	Number of Suppliers	Number of Suppliers within Allowable Charge Range*				Number of Suppliers	Number of Suppliers R		
		< $1,000	$1,000 - $5,000	$5,000 - $10,000	$10,000 - $50,000	$50,000 +		< $1,000	$1,000 - $5,000	$5 $1
Jan-10	11,467	7,322	2,374	883	551	337	10,081	6,668	2,006	
Feb-10	11,480	7,297	2,399	927	512	345	10,149	6,694	2,009	
Mar-10	11,932	7,333	2,669	973	564	393	10,647	6,796	2,245	
Apr-10	11,879	7,438	2,557	980	552	352	10,453	6,724	2,159	
May-10	11,954	7,585	2,528	953	531	357	10,378	6,703	2,123	
Jun-10	12,361	7,817	2,650	962	545	387	10,716	6,858	2,285	
Jul-10	12,377	7,958	2,560	976	524	359	10,780	7,097	2,149	
Aug-10	12,570	8,135	2,551	965	559	360	10,811	7,043	2,193	
Sep-10	12,392	8,045	2,486	949	538	374	10,774	7,008	2,168	
Oct-10	12,163	8,013	2,380	942	494	334	10,474	6,931	1,997	
Nov-10	11,765	7,778	2,255	913	480	339	10,275	6,858	1,917	
Dec-10	11,931	7,691	2,362	970	515	393	10,374	6,783	2,012	
Jan-11	11,485	7,633	2,331	791	475	255	10,317	6,838	2,042	
Feb-11	11,502	7,608	2,330	781	520	263	10,270	6,823	2,023	
Mar-11	11,859	7,566	2,616	860	516	301	10,669	6,821	2,280	
Apr-11	11,546	7,393	2,531	834	506	282	10,430	6,810	2,115	
May-11	11,814	7,530	2,641	825	533	285	10,545	6,782	2,235	
Jun-11	12,100	7,823	2,626	824	523	304	10,697	6,905	2,248	
Jul-11	12,005	7,881	2,550	785	503	286	10,573	6,894	2,179	
Aug-11	12,082	7,803	2,672	801	509	297	10,817	6,963	2,299	
Sep-11	11,981	7,766	2,639	760	525	291	10,722	6,981	2,209	
Oct-11	11,498	7,625	2,410	750	454	259	10,380	6,849	2,073	
Nov-11	11,049	7,363	2,204	763	452	267	10,089	6,723	1,953	
Dec-11	11,140	7,263	2,323	769	498	287	10,213	6,700	2,003	

[5]This provides an unduplicated count of unique suppliers that had allowed charges in these areas during a month; the suppliers furnishing items in a given month may not be the same suppliers furnishing items in another month.

* Allowable charge ranges exclude the upper bound

Question: **For how many bidders in Round 1 did CMS adjust the capacity to arrive at the final number of contract suppliers?**

Answer: CMS examines bidders' capacity estimates by item, not by product category. CMS adjusted the capacity of at least one item for 256 of the 356 contract suppliers. For the 256 suppliers that had at least one capacity estimate adjusted, 56 percent of the items were not adjusted, 16 percent of the items were reduced to 20 percent of demand for the item in the competitive bidding area, and 28 percent were adjusted to the bidder's historic levels.

Question: **You noted that the Cramton auction was designed for commodities and not for "services to patients in their homes". Since the benefit specifies that payment is for the equipment and Medicare does not pay for services, is this a change in policy? If so, will CMS identify which services suppliers are required to provide?**

Answer: Medicare's payment for the equipment includes costs that are associated with furnishing the equipment in accordance with Medicare requirements, such as the supplier standards, quality standards, and coverage policies. For example, Medicare's rental payment for a hospital bed includes delivery, set-up, patient training, and any needed repairs. These requirements apply regardless of whether the equipment is paid under the fee schedule or the competitive bidding program; there has been no change in policy.

Question: **Can CMS explain the impact on state Medicaid recipients and their access to DME items and services as a result of the bidding program? If there is a drastic reduction in the number of DME providers in the United States caused by the current bid program, and rates are reduced significantly, can you explain how this will not negatively impact patients' access to DME in Medicare, Medicaid, and private insurance plans?**

Answer: CMS has not heard complaints of access problems for Medicaid recipients resulting from the competitive bidding program or observed a drastic reduction in the number of DMEPOS suppliers. Please see Table 1 (above) for the number of suppliers that furnished durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items in the Round 1 Rebid competitive bidding areas and comparator areas in 2010 and 2011. CMS continues to monitor DME supplier data to monitor any change in the number of suppliers.

Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
May 9, 2012

Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services

Mr. Roskam & Mr. Nunes

Mr. Roskam

As the competitive bidding program for DMEPOS continues to move forward, we have heard from more and more companies in the Chicago land area that may be forced to close due to losing bids in round 2 because of the parameters of the existing competitive bidding program. During your testimony you stated that CMS reviews the bids and scrutinizes suppliers. However, I have heard anecdotally that, in 2011 (the first year of the competitive bidding program), a single supplier went from providing approximately 41 to 64 percent (Cincinnati) and 51 to 81 percent (Pittsburgh) of certain supplies in a competitive bidding area and that several winning suppliers have not provided *any* products in these (and other) areas during the first year of the program.

Question: **Why is a single supplier dominating a number of markets and some suppliers not providing products at all? This would seem to lead to the conclusion that other suppliers have either not been able to meet their commitments, have had to close, or the winning bidders were not thoroughly screened, can you speak to which is true?**

Answer: CMS awards contracts to qualified suppliers with sufficient capacity to meet beneficiary demand for each product category in each competitive bidding area. The competitive bidding program contracts do not guarantee a set volume of business. When contracts go into effect, the contract suppliers must compete against each other for Medicare beneficiaries' business on the basis of quality and customer service.

Question **What penalties are levied on contracted suppliers who do not come close to meeting their bid capacities?**

Answer: The competitive bidding program contracts require each contract supplier to furnish items in its contract to any beneficiary who lives in or visits the competitive bidding area and requests those items from the contract supplier. If a supplier does not meet its contractual obligation, CMS may take one or more of the following actions: require the contract supplier to submit a corrective action plan; suspend the contract supplier's contract; terminate the contract; preclude the contract supplier from participating in the competitive bidding program; revoke

the supplier's billing privileges; or impose other remedies allowed by law. (See 42 CFR 414.422(g).)

The capacity estimates in a supplier's bid represent the maximum number of items the supplier estimates it could furnish annually if awarded a contract. CMS validates these capacity estimates during the bid evaluation process and awards contracts to more than enough suppliers to meet beneficiary demand. Because of statutory requirements that guarantee beneficiary choice, beneficiaries may choose to obtain their items from any contract supplier. Therefore, competitive bidding program contracts do not guarantee any set volume of business. Thus, a contract supplier that furnishes items in its contract to any beneficiary who requests them is in compliance with competitive bidding program rules even if that supplier has not furnished the maximum number of items in its bid.

Question: **I am concerned that the market will contract to a point where there are only a handful of DME providers left which could potentially lead to higher prices and less competition. What is CMS doing to prevent this from occurring?**

Answer: The competitive bidding program includes numerous provisions to ensure a robust, competitive market. For example, CMS selects more than enough suppliers to meet demand. As a general rule for contract supplier selection purposes, we do not credit more than 20 percent of the total Medicare demand for a product category in a competitive bidding area to any one supplier, meaning at least five suppliers serve most product categories in most areas. Also, CMS has taken specific steps to ensure that small suppliers have the opportunity to be considered for participation in the competitive bidding program. These steps include offering small suppliers the opportunity to form networks, a small supplier target, and not requiring suppliers to submit bids for all product categories.

Question: **Why did the agency not exclude suicide bids from the single payment amount (for example, where a supplier did not accept a bid amount, yet their bid remained in the single payment amount)? Why are bids not binding on suppliers?**

Answer: Only legitimate, sustainable bids were included in the single payment amount determinations. We recognize the need to ensure that the single payment amounts are appropriate and viable, and through our bid evaluation process, identified and eliminated any irrational, infeasible bids. All bids are screened and evaluated to ensure that they are bona fide. 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.

The Medicare statute does not provide any authority that would permit CMS to require winning suppliers to accept contracts. This is consistent with other provisions of the Medicare statute that make supplier participation in Medicare voluntary. Although the statute does not provide any authority for requiring suppliers to accept contracts, it is not clear that such authority is needed. In the Round 1 Rebid, 92 percent of suppliers that were offered contracts accepted those contracts. CMS analyzed the bid amounts for the most commonly used items in each product category from suppliers that chose not to accept any contract and found that approximately the same number of bids were above and below the single payment amounts. Such results indicate the single payment amounts are set at an appropriate level based on the bids received during the Round 1 Rebid. There also have been no indications of any beneficiary access problems, and CMS has not had to add any new suppliers to meet demand.

During your testimony you also spoke to conversations you have had with Peter Crampton (sic) about his letter signed by 244 economists and 4 Nobel Laureates pointing to flaws in the competitive bidding program. Further, Tom Bradley, Chief of Medicare Cost Estimates for the Congressional Budget Office while attending a briefing stated the following, "If they (CMS) don't change the mechanism they use, I think there is a high probability of failure in the near future. There is a near certainty of failure sometime down the road".

Question: **What were the specific concerns you had with Mr. Crampton's proposal relating to Market Clearing Price and binding bonded proposals, which is the accepted standard in other federal government contracting bidding processes? If others have stated the program cannot stand as it is currently implemented why would CMS not adopt a different method before expanding the program to an additional 91 areas?**

Answer: The current competitive bidding program is the successful result of decades of research and testing by economists and health policy experts. The program offers improved value to Medicare and taxpayers by using prices set through competition and ensuring access to quality items furnished by licensed, accredited suppliers that must meet strict quality and financial standards. As indicated in CMS testimony, the program has already yielded significant savings for taxpayers and Medicare beneficiaries while preserving beneficiary access and health status outcomes.

CMS staff reviewed a January 16, 2012 version of the "market pricing" program. We have grave concerns with many aspects of this proposal. For example, as discussed in the following bullets, we are concerned that this proposal would result in auction failure in all, or nearly all areas, would not result in accurate pricing in those auctions if any were successful, and would not guarantee beneficiary access to needed items.

- Auction Failure: The program would result in nearly universal auction failure. Bidders' capacities would be artificially capped at historic levels (for suppliers in the area) or a minute fraction of demand (for suppliers not in the area). In effect, it assumes that suppliers would be unable to expand their businesses. The sum of all of the historic capacities of eligible, legitimate suppliers would be unlikely to reach the demand target. At a minimum, contracts would need to be awarded to every supplier in the area currently furnishing the item. Suppliers would know this ahead of time since the capacity of every bidding supplier would be disclosed prior to bidding. There would be no incentive to bid competitively since suppliers would be virtually assured of being awarded a contract.
- Inaccurate pricing. Bidders would only submit bids for one item in the product category. Prices for the other items would be based on the price for the lead item. Prices could end up too high or too low for the other items, resulting in lost savings or access problems.
- Failure to guarantee access: The program fails to guarantee beneficiary access. In fact, it explicitly permits a supplier to turn beneficiaries away if the predicted demand in an area has been met even if that supplier has not furnished up to the level in its bid.

We note that the auction model used in the January 16, 2012 proposal has been used for commodities like diamonds and timber but has never been tested in the healthcare arena. This is a concern since applying this model could have a significant effect on the quality of items and services Medicare beneficiaries receive, Medicare expenditures, and the Medicare DMEPOS market overall.

Finally, we note that this proposal would take many years to implement due to nced to comply with the requirements of procedural laws like the Administrative Procedures Act and the Paperwork Reduction Act and the time it would take to develop the infrastructure to support the program. These delays could have serious cost implications since the current DMEPOS competitive bidding program is working to replace Medicare's outdated fee schedule amounts with fair payment amounts. The Department of Health and Human Services' Office of Inspector General (OIG)[6], 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. CMS' Office of the Actuary (OACT) estimates that the current DMEPOS competitive bidding program will save the Medicare Part B Trust Fund $25.7 billion between 2013 and 2022. Beneficiaries are expected to save an estimated $17.1 billion due to the reduction in coinsurance and the downward effect on premium payments.

[6] 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.

Committee on Ways and Means
Subcommittee on Health
Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
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Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services

Mr. Roskam & Mr. Nunes

Mr. Devin Nunes

Question: **After one year of competitive bidding for diabetic testing supplies, CMS claims that there was no evidence of negative health care outcomes for diabetes testing supply users. How confident is CMS that such negative health outcomes will not be apparent until 2013 or 2014 or later? Doesn't it take time for negative health outcomes to appear in a diabetes patient, who fails to be less adherent? Especially, higher mortality rates?**

Answer: CMS is monitoring both short term and long term health care outcomes for diabetic patients. Diabetes is a chronic disease, and the manifestations of the disease are not all immediate. However, the comprehensive nature of our monitoring of health outcomes and the sensitivity to detect changes would detect any acute changes that could occur. For example, a rise in emergency department visits or physician visits would be precursors to the more chronic changes that would impact health outcomes. As we have not seen an increase in any short term negative health outcomes, it is unlikely that there would be an increase in negative long term outcomes. Since our monitoring is ongoing, we will be able to detect as early as possible such long-term outcomes, should they occur.

Question: **The CMS report on Round 1 results showing that beneficiaries reported having more than enough supplies on hand and therefore did not need to obtain additional supplies when the program began. Does this indicate that mail order diabetic testing supply waste via auto-shipping is a major problem?**

Answer: Diabetes monitoring supplies have historically had high error rates. A recent report by the HHS Office of the Inspector General found that 76 percent of a sample of claims for diabetes test strips and/or lancets were improperly paid.[7] Our findings suggest that beneficiaries received excessive replacement supplies before they became medically necessary. While more investigation is

[7] http://oig.hhs.gov/oas/reports/region9/91102027.pdf

needed to verify the cause or causes of inappropriate distribution, waste via auto-shipping is a serious concern.

Question: **Outside of 1-800-MEDICARE how does CMS collect patient complaints about the competitive bidding program for diabetic testing supplies? Does CMS collect complaint data based on patients who complain to their pharmacists or suppliers regarding the competitive bidding program?**

Answer: CMS has a comprehensive monitoring program that includes the 1-800-MEDICARE call center; local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen; a formal complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues; and a CMS Competitive Acquisition Ombudsman who responds to complaints and inquiries from beneficiaries and suppliers about the application of the program. These CMS customer service entities follow an integrated inquiry and complaint management process to ensure that any person who contacts CMS about the competitive bidding program will be promptly assisted. CMS has conducted extensive outreach to beneficiaries, suppliers, referral agents, and beneficiary advocacy groups like the local State Health Insurance and Assistance Program (SHIP) offices so that they understand how to how to contact CMS with any questions, concerns, or complaints about the program.

Question: **Early data seemed to indicate that, in the competitive bidding areas, utilization of mail order pharmacies for diabetic testing supplies is decreasing, while the utilization of retail pharmacies for these supplies is increasing. This would seem to indicate that mail order suppliers in the competitive bidding areas are unable to meet the demands of the beneficiaries who need diabetic testing supplies. Is this the case? If it is, wouldn't it make sense to maintain access to diabetic testing supplies at retail pharmacies as a necessary safety valve in the competitive bidding program?**

Answer: CMS has not seen any evidence that the Round 1 Rebid mail order contract suppliers have capacity problems. However, manufacturers and suppliers have stated to CMS on numerous occasions that the option for beneficiaries to obtain diabetic supplies from local pharmacies with licensed pharmacists in house who can provide instructions and guidance to beneficiaries related to their testing needs is important and should be preserved. In recognition of these concerns, CMS has elected not to include retail (non-mail order) diabetic supplies in any currently scheduled competitions. We note that retail diabetic supplies are a high-volume item with over $500 million in annual Medicare allowed charges and that there is a large disparity between the Medicare fee schedule amount for retail diabetic supplies and the Round 1 Rebid single payment amounts.

Question: **Diabetic testing supplies obtained at a retail pharmacy are not currently included in the competitive bidding program. Therefore, beneficiaries can still obtain their diabetic testing supplies at their local pharmacy. Mandating that diabetic testing supplies could only be obtained through mail order suppliers would mean that the pharmacist and the beneficiary would no longer meet face-to-face, as they do now. Would such a restriction increase the possibility that the beneficiary may become less adherent with his or her medications or that other health care issues may not be identified because they are no longer meeting face-to-face?**

Answer: Please see answer to previous question above.

Committee on Ways and Means
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Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program
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Questions for the Record for
Laurence Wilson, Centers for Medicare and Medicaid Services

Mr. Tiberi

Mr. Tiberi
I would like to request additional information regarding Round 1 of the DME competitive bidding program in order for Congress to better evaluate the program and assess the validity of concerns raised by some. Please provide the following information:

1. Provide the charts with the data appended that track the utilization for each DME competitive bidding product category, from 2008 to present, for each Competitive Bid Area (CBA) and its comparator city. Provide a full set of charts as follows for each product category:

A. Percent of the Access Group (e.g. Cardio-Pulmonary Narrow, Diabetic, Sleep Disorders, a set for each one) purchasing or renting (the product category, such as Oxygen, Mail Order Diabetes Supplies, CPAP, etc.);

B. Percent of the Medicare A/B fee for service (FFS) population purchasing or renting (a set for each product category); and

C. A set of graphs for each of the above that reflects, in total, all CBAs and comparator cities combined.

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html . These charts are based on 100 percent of Medicare claims provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened. The health status health outcomes being monitored include events such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. As shown in the charts, fluctuations in outcomes match closely in competitive bidding

areas and comparison areas both before and after the start of the competitive bidding program. Historic seasonal trends also continue to be reflected. There have been no changes in beneficiary health status outcomes resulting from the competitive bidding program observed to date.

Comparing trends in claims utilization data alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of claims does not necessarily provide a reliable measure of the number of medically necessary items furnished to Medicare beneficiaries. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. The results of CMS's real-time claims monitoring is also supported hy the low number of beneficiary complaints the agency has received. For these reasons, we strongly believe that the best way to evaluate the program is to use the charts that are on the CMS website. We would be pleased to provide Members with a briefing to go over the health status outcomes in more detail and to explain the real time claims monitoring program methodology.

2. Provide, by product category and for each CBA and each comparator city, the number of unique Medicare Beneficiaries with a claim submitted, and, separately, a claim paid, for the following two time periods:

A. Date of Service from October 1 through December 31, 2010

B. Date of Service from October 1 through December 31, 2011

Answer: CMS has a strong commitment to ensuring that beneficiaries have continued access to quality equipment under the program. For this reason, we developed a comprehensive monitoring system to assess access and health outcomes in near real time. We monitor over 3,400 data points to ensure that Medicare beneficiaries who use a competitively bid item and those who have conditions that may warrant use of a competitively bid item have continued access and do not suffer adverse health outcomes as a result of the competitive bidding program. Charts that show program results are regularly updated and posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html. These charts are based on 100 percent of

Medicare claims and provide valid and reliable data about beneficiary health status outcomes, control for broader trends, and would indicate if beneficiary access or quality had been threatened.

Comparing trends in the number of beneficiaries for whom claims were submitted or paid alone before and after the program began may not provide a valid and reliable way to measure the impact of the competitive bidding program because the number of beneficaires for whom claims were submitted or paid does not necessarily provide a reliable measure of the number of Medicare beneficiaries who need or receive these items. For years, the Office of Inspector General has issued reports finding frequent, widespread problems in the DMEPOS industry like claims for services to deceased beneficiaries and claims for excessive or duplicate services. CMS has been working hard to combat fraud and has also been taking steps to reduce the very high claims error rate in the DMEPOS arena; however, many claims for fraudulent or unnecessary services have been paid. Comparisons of 2011-2012 claims data to previous years could mislead observers because they have not been controlled for effects such as expansion of targeted anti-fraud efforts.

To ensure that beneficiaries continue to have access to all needed DMEPOS items, CMS has taken the precautionary step of directly contacting beneficiaries in competitive bidding areas who had claims for mail order diabetes test strips and continuous positive airway pressure (CPAP) supplies before but not after program implementation. Through our direct beneficiary outreach, we determined that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. These targeted outreach efforts reflect the Agency's commitment to act on the health status outcomes information produced from our comprehensive claims monitoring system. This information is displayed in the charts available on the CMS website. We would be pleased to provide Members with a briefing to go over these health status outcomes in more detail and to explain the real time claims monitoring program methodology.

3. Provide for each product category in Rebid areas the number of unique DMEPOS suppliers that submitted a claim for a date of service in December 2010 and, separately, in December 2011 as follows:

A. Number of Contracted suppliers in each CBA submitting a claim;

B. Number of non-contracted suppliers in each CBA submitting a claim; and

C. For each comparator city, the number of suppliers submitting a claim.

Answer: The attached Excel document shows the number of unique DMEPOS suppliers with any allowed charges for competitively bid items in 2010 and 2011 in CBAs and comparator areas. We note that many of these suppliers had very small allowed charges. To help provide perspective about suppliers with a more meaningful presence in the area, we have also provided the number of unique DMEPOS suppliers with allowed charges for competitively bid items of at least $10,000 in these years.

4. Provide for the product categories of oxygen, CPAP and enteral nutrition, charts that track the health outcomes (https://www.cms.gov/DMEPOSCompetitiveBid/01A3_Monitoring.asp) of beneficiaries in each CBA and comparator city who:

A. Had a claim for the product category with a date of service between October 1, 2010 and January 31, 2011, and

B. Did NOT have a claim for the product category with a date of service between October 1, 2011 and January 31, 2012, and

C. Are not deceased.

Answer: CMS does not currently compile claims data in the manner requested. CMS understands the Subcommittee's interest in assessisng the health status of beneficiaries with a history of equipment use who no longer use the product. We note that it is difficult to measure "non-use" with Medicare claims data. Instead, we identify individuals that are not *billing* for a particular product. These people may have excess replacement supplies, may have reached the end of their billing period, or may no longer need the product. It is possible that these beneficiaries may have changes in health status over time. However, these changes could occur for many reasons which may not be related to competitive bidding. This will make the results of this analysis difficult to interpret. We have summarized two hypothetical examples below.

> Example 1: A beneficiary receives a CPAP device in 2010. Over the next few months, the person's health status improves and the CPAP device is no longer necessary. The beneficiary does not have a CPAP-related claim in 2011-2012. Since the beneficiary's health status has improved, he has decreased rates of emergency department utilization and fewer physician visits in 2011 compared to 2010. We cannot conclude that the beneficiary's improved health status outcomes are the result of the competitive bidding program.
>
> Example 2: In 2010, a beneficiary is in her 36th month of a rental period for a portable oxygen concentrator. Since Medicare pays for oxygen using a 36 month capped rental, the beneficiary does not have an oxygen-related claim between October 1, 2011 and January 31, 2012, even though she is continuing to receive oxygen. The beneficiary has severe COPD along with several other conditions, and her health status is deteriorating with age. The beneficiary visits the hospital more often in 2011 than 2010 as a result of her worsening health status; however, we cannot use claims data to conclude that this is related to competitive bidding.

CMS agrees that it is very important to monitor access and outcomes for all beneficiaries who are likely to need a competitively bid item based on their medical needs, including beneficiaries who do not have a claim for the item. The CMS real-time claims analysis program is currently tracking this information; the relevant information can be found on the "Access Group" charts in the health status outcomes charts on the CMS website (see: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html). The "Access Group" tracking has been

designed to control for non-competitive bidding program effects and provide an accurate picture of program results.

Despite the difficulty in measuring the "non-use" of a product, we hve estimated the cost of compiling the requested data to be approximately $20,000 to $40,000. The compilation would take at least several weeks.

Question Attachments
Attachment for Mr. Tiberi and Mr. Price Q3 Complex WC Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Complex Rehabilitative Power Wheelchairs

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	1	3	3	5	1	4	3	6	3
2011	2	0	2	1	0	4	4	0	3

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	0	2	0	0	0	1	1	1	1
2011	0	0	0	0	0	0	1	0	2

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	1	10	6	3	2	4	3	2	4
2011	0	0	3	1	0	4	4	0	7

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	1	2	1	0	1	0	1	0	3
2011	0	0	0	0	0	1	2	0	0

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	1	1	3	1	0	4	3	2	6
2011	1	1	2	0	1	1	2	0	5

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	1	0	1	1	0	1	0	0	0
2011	0	0	0	0	0	0	0	0	1

Attachment for Mr. Tiberi and Mr. Price Q3 CPAP Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: CPAP/RAD Devices, Supplies, and Accessories

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	29	244	176	33	202	235	34	149	206
2011	29	164	166	33	154	252	38	97	202

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	22	28	35	19	23	47	23	24	35
2011	23	15	38	20	11	48	29	13	40

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	55	583	434	41	179	207	37	698	636
2011	58	424	434	42	141	185	41	519	651

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	35	63	92	25	18	46	22	43	59
2011	42	27	104	25	7	45	29	12	58

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	33	463	284	56	134	482	31	282	187
2011	38	358	272	60	108	465	34	222	188

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	19	44	41	35	16	102	20	30	32
2011	24	18	43	35	8	100	24	10	29

Attachment for Mr. Tiberi and Mr. Price Q3 Diabetic Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Mail Order Diabetic Supplies

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	9	262	211	9	221	194	14	210	210
2011	10	N/A	217	16	N/A	208	18	N/A	207

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	7	82	47	6	57	51	7	55	52
2011	9	N/A	58	12	N/A	52	11	N/A	53

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	10	318	301	8	192	198	13	267	270
2011	12	N/A	314	10	N/A	197	17	N/A	273

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	8	88	82	6	45	46	8	70	64
2011	11	N/A	89	8	N/A	51	11	N/A	61

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	11	234	225	9	184	316	7	200	165
2011	13	N/A	223	21	N/A	335	11	N/A	185

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	7	56	54	4	43	99	3	43	39
2011	8	N/A	55	9	N/A	111	8	N/A	40

Attachment for Mr. Tiberi and Mr. Price Q3 Enteral Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Enteral Nutrients, Equipment, and Supplies

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	23	58	63	12	66	62	25	64	91
2011	29	N/A	60	18	N/A	56	27	N/A	82

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	16	20	23	7	22	27	17	22	31
2011	18	N/A	24	11	N/A	24	15	N/A	29

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	36	180	197	25	57	54	42	219	139
2011	42	N/A	194	25	N/A	55	42	N/A	131

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	21	61	88	16	17	23	29	88	44
2011	30	N/A	87	13	N/A	20	34	N/A	43

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	19	86	79	24	53	151	17	82	71
2011	21	N/A	72	28	N/A	159	22	N/A	69

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	9	22	36	10	21	71	15	24	36
2011	10	N/A	31	10	N/A	65	17	N/A	36

Attachment for Mr. Tiberi and Mr. Price Q3 Hospital Bed Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Hospital Beds and Accessories

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	18	194	162	18	148	128	17	141	155
2011	19	160	155	17	114	130	22	117	153

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	8	23	22	5	23	18	6	24	24
2011	13	8	24	8	12	18	9	10	21

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	26	530	443	24	131	134	32	606	390
2011	26	399	443	25	100	129	35	448	359

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	14	78	86	10	18	29	19	89	47
2011	20	32	78	13	4	27	25	41	47

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	16	315	171	29	186	441	12	382	233
2011	19	227	164	34	132	409	15	306	236

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	5	30	18	13	21	102	7	38	26
2011	8	14	17	15	10	96	11	17	24

Attachment for Mr. Tiberi and Mr. Price Q3 Oxygen Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Oxygen, Oxygen Equipment, and Supplies

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	60	206	207	40	207	239	43	191	276
2011	61	200	201	39	178	236	44	158	236

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	43	10	33	28	24	47	34	15	50
2011	40	5	33	27	15	43	34	12	47

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	82	627	570	42	207	239	92	722	682
2011	91	532	557	45	181	234	95	571	639

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	70	65	111	39	14	53	74	91	66
2011	71	38	117	36	12	50	72	51	64

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	62	436	278	60	247	611	38	351	284
2011	66	369	267	64	194	564	43	304	274

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	40	38	43	43	33	138	26	29	29
2011	38	20	41	44	27	141	34	17	31

Attachment for Mr. Tiberi and Mr. Price Q3 Standard WC Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Standard Power Wheelchairs and Scooters

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	17	61	68	19	50	49	14	48	52
2011	22	20	60	17	14	44	14	7	39

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	14	30	27	11	22	19	9	17	17
2011	11	0	13	9	0	10	10	0	5

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	28	209	159	7	49	58	15	166	128
2011	30	44	136	11	15	53	18	49	107

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	21	119	77	5	17	36	9	51	56
2011	25	0	32	4	0	23	10	2	33

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	11	94	70	11	34	181	33	229	123
2011	13	33	51	14	6	143	30	52	96

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	8	32	26	10	9	94	22	99	54
2011	8	0	17	5	0	45	23	0	24

Attachment for Mr. Tiberi and Mr. Price Q3 Surfaces Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Support Surfaces, Miami

Suppliers with contract allowable charges			
	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	13	195	60
2011	14	102	51

Suppliers with at least $10,000 in allowable charges in the product category in the year			
	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	6	63	12
2011	8	20	13

Attachment for Mr. Tiberi and Mr. Price Q3 Walker Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Walkers and Accessories

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	25	254	243	14	295	250	55	238	248
2011	25	116	249	19	100	234	57	97	258

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	6	5	12	3	8	10	3	11	7
2011	6	0	11	3	0	9	5	0	7

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	52	640	644	19	219	198	34	886	610
2011	55	227	628	23	92	177	36	395	595

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	12	27	33	1	11	14	12	34	22
2011	15	0	32	5	1	12	15	0	21

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	28	402	225	49	218	664	19	421	253
2011	35	221	232	49	93	600	21	191	254

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	8	9	14	2	9	51	4	10	11
2011	9	0	15	4	0	46	6	0	11

Attachment for Mr. Tiberi and Mr. Price Q3 WC Parts Suppliers Year

Supplier Counts by 10-Digit Provider Transaction Access Number: Wheelchair Accessories and Replacement Parts

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	27	154	145	25	111	101	19	116	117
2011	27	122	124	26	88	110	19	99	114

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Charlotte, NC-SC		Comparator: Virginia Beach, VA-NC	CBA: Cincinnati, OH		Comparator: Indianapolis, IN	CBA: Cleveland, OH		Comparator: Columbus, OH
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	9	12	20	10	13	17	6	11	15
2011	11	7	23	7	6	14	7	11	10

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	33	398	349	12	112	109	24	422	302
2011	36	284	294	14	99	95	22	369	269

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Dallas, TX		Comparator: Houston, TX	CBA: Kansas City, KS-MO		Comparator: Oklahoma City, OK	CBA: Miami, FL		Comparator: Tampa, FL
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	18	52	38	5	12	25	9	48	41
2011	17	29	42	4	4	25	11	36	35

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	13	217	140	27	133	359	41	330	215
2011	17	161	124	29	103	313	37	244	193

Suppliers with at least $10,000 in allowable charges in the product category in the year

	CBA: Orlando, FL		Comparator: Jacksonville, FL	CBA: Pittsburgh, PA		Comparator: Detroit, MI	CBA: Riverside, CA		Comparator: San Diego, CA
	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers	Number of Contract Suppliers	Number of Non Contract Suppliers	Number of Suppliers
2010	8	19	13	10	5	45	18	50	36
2011	5	15	16	9	5	43	23	28	36

Public Submissions For The Record
Center for Regulatory Effectiveness

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May 9, 2012

The Honorable John P. Holdren, Ph.D.
Assistant to the President for Science and Technology
Director, Office of Science and Technology Policy
725 17th Street, NW
Washington, DC 20502

> *The CMS competitive bidding program violates all of the principles* [of Executive Order 13563], *especially the principles of transparency and of basing regulations on the best available science. Indeed, the current program is the antithesis of science and contradicts all that is known about proper market design.*

Dear Dr. Holdren:

The above quote is from a letter signed by over 240 academicians including several Nobel laureates to President Obama evaluating a Centers for Medicare and Medicaid Services (CMS) program for the competitive acquisition of Durable Medical Equipment.[1]

The letter writers were not alone in their criticism of the science underlying implementation of CMS' DME competitive bidding program. The Congressional Budget Office's (CBO's) Chief of Medicare Cost Estimates, speaking at a Medicare Auction Conference co-sponsored by the University of Maryland and the National Science Foundation[2] summarized the program's problems more bluntly,

> *If they don't change the mechanism they use, I think there is a high probability of failure in the near future. There is near certainty of failure sometime down the road.*[3]

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[1] Letter from 244 Concerned Auction Experts, 17 June 2011, p. 1, *available at* http://thecre.com/pdf/Letter_from_244_Concerned_Auction_Experts.pdf.

[2] Medicare Auction Conference, 1 April 2011, Agenda *available at* http://www.cramton.umd.edu/papers2010-2014/medicare-auction-conference-program.pdf.

[3] Transcript, Medicare Auction Conference, University of Maryland, Final Panel: "What Have We Learned?" April 1, 2011, p. 5, *available at* http://www.cramton.umd.edu/papers2010-2014/medicare-auction-conference-final-panel-562.rtf.

When over two-hundred professors describe a federal program as "the antithesis of science" and when a senior CBO official warns that there is the "near certainty of failure" for a major Medicare program, White House oversight and intervention is a necessity. I say this as someone who has served five presidents and who recently authored a law review article providing the history of Presidential regulatory review.[4]

I am attaching a paper which analyzes the CMS competitive bidding program from a game theory perspective. The paper also contrasts the CMS program with the excellent work done by the Federal Communications Commission (FCC) in developing an auction system which has taken advantage of modern scientific techniques to test and improve their processes.

The attached paper notes that EO 13563, in discussing the White House's Scientific Integrity memorandum, states that "each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions." The President's Scientific Integrity directive itself requires that agencies use "well-established scientific processes, including peer review where appropriate...." Developing an efficient auction is a scientific exercise. The Center for Regulatory Effectiveness, acting in its capacity as a regulatory watchdog, is working to ensure that agencies adhere to the "good government laws" including the Scientific Integrity Memorandum.

The paper's recommendation is that:

$ The federal government conduct a federally-sponsored laboratory simulation of CMS' DME bidding rules to assess their efficiency and determine how they can be reformed to the benefit of the nation's taxpayers and Medicare beneficiaries.

The purpose of conducting a clinical trial would be to allow a fair comparison of how the CMS bidding rules affect the price to taxpayers of durable medical equipment and services. The clinical test could also address the differentiation between the quality of the services received by a beneficiary through the CMS competitive bidding program relative to the quality of services beneficiaries receive paid for under a price schedule. The clinical test also needs to evaluate the sustainability of the auction process relative to other sets of rules. On this point, I reiterate the Congressional Budget Office's warning that CMS's current bidding system has a "near certainty of failure."

Auction failure would mean that life-saving home medical equipment and services would either be cut-off or provided at an increased cost to millions of Medicare beneficiaries resulting in an enormous human toll and in a financial toll for taxpayers from increased emergency room visits, hospitalizations and nursing home care.

The warnings by everyone from CBO to hundreds of distinguished economists have been made. The dots have been connected.

---

[4] Jim Tozzi, "OIRA's Formative Years: The Historical Record of Centralized Regulatory Review Preceding OIRA's Founding," 63 Admin. L. Rev. (Special Edition) 37 (2011), *available at* http://www.thecrc.com/pdf/20111211_ALR_Tozzi_Final.pdf.

The President's Scientific Integrity Memorandum assigns the Director of the Office of Science and Technology Policy "the responsibility for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes." Consequently, I will be contacting your office to arrange a meeting with yourself or a designated appointee to discuss the paper and agency adherence to the Scientific Integrity directive.

Sincerely,

Jim Tozzi
Member, Board of Advisors

cc: The Honorable Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs

Attachment – "Auctioning Healthcare: The Need for a Clinical Trial of CMS' Competitive Bidding Program for Durable Medical Equipment"
http://www.thecre.com/pdf/AuctioningHealthcare.2012.CRE.pdf

Council For Quality Respiratory Care

CQRC COUNCIL FOR QUALITY RESPIRATORY CARE

Statement for the Record Submitted on Behalf of the Council For Quality Respiratory Care

U.S. House of Representatives Subcommittee on Health Committee on Ways and Means

Hearing on the Medical Durable Medical Equipment Competitive Bidding Program

May 9, 2012

The Council for Quality Respiratory Care (CQRC) appreciates the opportunity to submit this written statement for the record of the May 9, 2012, House Ways and Means Health Subcommittee hearing examining the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS) Competitive Bidding Program. CQRC applauds the Subcommittee's Leadership and Members for holding this hearing to learn more about the impact of the program on patients, suppliers, and Medicare expenditures.

The CQRC supports the competitive bidding program for durable medical equipment, if implemented appropriately. We oppose efforts to delay or repeal the program that would result in cuts to the home respiratory therapy benefit.

The CQRC is a coalition of the nation's eight leading home oxygen therapy providers who have served beneficiaries in the Medicare DMEPOS program for more than 30 years, as well as DMEPOS manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 (the majority) of the more than one million Medicare beneficiaries who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Our members also employ approximately 36,000 people in the United States.

The CQRC has sought to work with CMS to address implementation issues identified during Round I. It is important to evaluate Round I and modify the requirements for Round II to address problems that arose during that initial phase of the program.

We strongly urge the Subcommittee to monitor the Round II competitive bidding process to ensure the bidding requirements are applied to all bidders.

In Round I, not all contract suppliers were able to provide services on day one of the contract period. Our members were required to cover the gap to ensure beneficiaries received their life-sustaining oxygen therapy as Round I went into effect because some winning bidders did not provide services in the CBAs. In some instances, these suppliers offered to sell their contracts or companies to our members because they did not intend to provide services in the CBAs. This practice results in higher overall costs and threatens access to care for beneficiaries.

These providers did not meet the CMS requirement that bidders "get licensed" and "get accredited" and be ready to provide services on day one. CMS required for Round I and has reiterated the requirement for Round II that it will award contracts only "to suppliers that have all state licenses at the time the bid is submitted…Every location must be licensed in each state in which it provides services." If a bidder has "only one location and [is] bidding in a CBA that includes more than one state, [it] must have all required licenses for every state in that CBA." If it has more than one location and is "bidding in a CBA that includes more than one state, [the] company must have all required licenses for the product category for every state in that CBA." CMS also requires suppliers to "be accredited for all items in a product category in order to submit a bid for that product category." Most importantly, "[e]ach contract supplier must be ready to provide services in the CBA [competitive bidding area] or nationwide…on day one of the contract period."

If a bidder does not meet the CMS bidding requirements, it should not be permitted to hold or sell the contract and the bid amount should be recalculated to account for the change. Based upon the experience of our members, it appears that CMS has not enforced this requirement; otherwise, all of the winning bidders that have approached our members would have provided services in the CBAs in which they won contracts.

CQRC looks forward to working with Congress to ensure a rational, fair, and effective solution to the severe problems caused by current auditing activities. Should you have any further questions, please do not hesitate to contact Kathy Lester at (202) 457-6000.

CQRC Members

Aerocare Holdings, Inc.
American HomePatient, Inc.
Apria Healthcare
Lincare Holdings
Pacific Pulmonary Services
Rotech Healthcare, Inc.
Philips Home Healthcare Solutions
ResMed Inc.

Dr. Lawrence I Brant

Name: Dr. Lawrence I Brant

Address: 10248 El Caballo Court, Delray Beach, FL 33446

Phone Number: Home: 561-637-4003

Contact E-mail Address: lawrenceibrant@bellsouth.net

Title of Hearing: Medicare Durable Medical Equipment Competitive Bidding Program
Wednesday, May 09, 2012

Dear Ways and Means, Health Committee Members,

I am an eighty year old Medicare beneficiary, with type 2 diabetes and I am a victim of Round One of Medicare's bidding program. I have used diabetic testing supplies daily for the past 12 years and I reside in Delray Beach, Florida, part of the Miami Bidding Area. I felt compelled to submit written comments to set the record straight about my ordeal trying to get diabetic supplies from bid winners in my area. I am now receiving supplies, hand delivered from a local non-winning provider, but I have concerns when the national mail order program begins next year and my current provider will not be able to hand deliver my diabetic testing supplies anymore.

For years I never worried about receiving my diabetic testing supplies, because my son owned an accredited home medical company in South Florida. Unfortunately, my son's company was awarded a contract in the Oxygen category, but ended up closing his company on April 30, 2011; and that's when my problems began.

Despite testimony in your hearing from Mr. Laurence Wilson, I did not have "stockpiles of diabetic testing supplies on my shelf." As a matter of fact, even though my endocrinologist gave me a prescription to test twice a day (which I sometimes do), my own son refused to provide me and bill Medicare that quantity. That is because, as my son explained, the doctor's notes did not specifically detail the precise wording for medical need in her notes required by auditors. I know that Medicare previously audited my simple one-test-a-day order and on several quarterly supplies I received, my son's company was never paid.

When the last 90 day supply provided by my son's company began to run out, I could not find a bid winner willing to provide my brand. I repeatedly called the 1-800-MEDICARE number and was given a list of companies that were supposed to help me. Some bid winners did not answer their phones and others just had an answering machine. Finally, one company contacted me back, but said that they could not provide my brand of strips. I was very surprised because about four years earlier, I had to give up the brand my doctor first prescribed. It was a very popular brand advertised on television, but about four years before competitive bidding began, my son told me that cuts in Medicare reimbursement meant he would have to take a fifty dollar loss for my quarterly supplies.

My son switched me to a brand that he said that he would not take a loss on and it worked very well. Unfortunately, the one bid winner that was willing to work with me said that he could not provide me my regular brand of testing strips because it cost more than the Medicare reimbursement. My son told me that the bid winners are required to provide the brand I need and that I should call 1-800-MEDICARE to complain. I called back 1-800-MEDICARE several times to complain and was redirected over and over again but was unable to record my complaint with anyone.

Desperate for my diabetic testing supplies, I decided to switch to the brand now offered from the bid winner and it did not work properly and forced me to waste test strips. The glucometer was very cumbersome, bulky and hard to use. I wasted one out of every three strips because if you did not hit the blood on the tip of the strip properly, it did not work. I would have called back Medicare to complain, but is anyone listening?

My son ended up contacting the manufacturer for the brand that I have used for the past four years, and I was referred to a company willing to drive the supplies to my home, and therefore bill Medicare at the non-bid rate. Unfortunately I am told that "loophole" will end when the program expands nationally on July 1, 2013. Then what am I supposed to do?

Can you please have Mr. Wilson answer that question for me?

I kindly ask the committee members to contact beneficiaries like me from Round One and find out what we think about Medicare's bidding program and consider changes to the program so I do not have to relive the same scenario next year.

Respectfully submitted,

Dr. Lawrence I Brant
Delray Beach, Florida

Health Industry Distributors Association

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

Statement

of the

Health Industry Distributors Association (HIDA)

to the

House Ways & Means Health Subcommittee

Medicare's Competitive Bidding Program for

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

May 23, 2012

On behalf of the interests of over 600 medical-surgical products distributor companies operating throughout the United States, the Health Industry Distributors Association (HIDA) commends the Ways & Means Health Subcommittee for convening a hearing on Medicare's competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to explore the program's impact on patients and providers.

Founded in 1902, HIDA is the professional trade association representing medical-surgical products distributors. Our members deliver life-saving healthcare products to more than 220,000 points of care including over 195,000 physician offices, 5,700 hospitals, and 16,000 nursing home and extended care facilities throughout the nation. HIDA's members are committed to promoting safety and cost savings within the healthcare supply chain.

The majority of distributors are small businesses. Over a quarter of the industry earns annual revenues under $1 million dollars. The healthcare distribution sector employs 65,000 people nationwide and ranked 39th out of 52 U.S. industries in relative annual profit margins by Fortune magazine. Distributors' average 1.3% annual profit margin is among the lowest in healthcare, requiring distributors to operate at extremely high levels of efficiency.

HIDA is committed to efforts to ensure that Medicare beneficiaries, specifically those residing in skilled nursing facilities (SNFs), continue to have uninterrupted access to life-sustaining medical products. As such, we write to express our concerns about the competitive bidding program's impact on SNFs and the patients they care for. Specifically, HIDA recommends:

- A third party validated study of the competitive bidding program's application to and impact on SNFs be conducted prior to the program's expansion nationwide; and
- The exclusion of enteral nutrients, equipment and supplies from Round Two of the competitive bidding program until the program's impact on SNFs and their patients is fully evaluated and understood.

Transitioning to a competitive bidding program for DMEPOS items and services raises many serious questions related to cost, access and beneficiary protection. SNF patients are among the nation's most ill and frail. They

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require 24/7 direct clinical coordination and care by nurses, doctors and other trained healthcare professionals, including long-term care specific enteral nutrient suppliers. The level of care required to support the healthcare needs of these patients must not be inadvertently threatened or compromised.

Impact on SNFs must be assessed

A third party validated study of the competitive bidding program's specific impact on SNFs must be conducted before the program further expands. The Government Accountability Office (GAO) recently released a report to Congress reviewing the first year of Medicare's DMEPOS competitive bidding program; however, it fails to provide a complete analysis of the program's specific impact on SNFs and their patients' access to quality enteral nutrition therapy. As CMS moves toward expanding the competitive bidding program from nine to 100 MSAs, it is essential to assess how the program has impacted this vulnerable patient setting.

It is apparent that the competitive bidding program was designed with the home care setting foremost in mind, yet SNFs care for the bulk of Medicare beneficiaries receiving enteral feeding for life-sustaining nutritional support. Mr. Laurence Wilson, CMS' Director of Chronic Care Policy, acknowledged this reality in response to a question posed by Representative Bill Pascrell (D-NJ) on the program's impact on SNFs during the May 9, 2012, Health Subcommittee hearing. Mr. Wilson stated that the only product category reimbursable under Medicare Part B impacting SNFs is enteral nutrition therapy (tube feeding).

Residents in SNFs often are more impaired than home care patients and they require a more complex regimen of care for enteral nutrition therapy than home care patients. Enteral patients in SNFs have dietary needs that change more frequently than most home care patients, thus requiring an enteral nutrition supplier that can readily address their special needs.

The competitive bidding program has interfered with a SNFs' ability to make decisions regarding the enteral nutrition needs of their residents. During the Round One rebid of the competitive bidding program a SNF had to submit and win a bid to continue providing enteral nutrition to its residents, or contract with a supplier from a list of bid winners in their respective metropolitan statistical area (MSA). Very few nursing homes won a bid to provide enteral nutrition to their own residents. Furthermore, many SNFs were forced to terminate long-standing relationships with their local long-term care specific enteral nutrient suppliers. These incidents raise a number of issues unique to the nursing home setting that must be evaluated prior to expanding the program nationwide.

Enteral nutrition therapy is not well-suited for competitive acquisition

Moving to a national competitive bidding program for DMEPOS items and services, specifically the inclusion of enteral nutrition therapy, raises many serious questions related to access, beneficiary protections, and market-based

competition. Taking these factors into consideration, HIDA recommends the exclusion of enteral nutrients, equipment and supplies from Round Two of the competitive bidding program until the program's impact on SNFs and their patients is fully evaluated and understood.

The level of care involved in delivering enteral nutrition therapy, commonly called tube feeding, must not be undermined by the competitive bidding process, nor should it compromise the life-sustaining nourishment to patients who cannot swallow because of severe or permanent medical problems. Patients are fed specialized nutritional formulas through a tube which is threaded through the nose, or a surgical opening, and leads directly to the stomach or intestine. Certain requirements must be satisfied in order to trigger Medicare Part B coverage of enteral nutrition in a SNF. First, the beneficiary must have a permanent functional impairment of the gastrointestinal tract. Second, enteral nutrition therapy must be deemed reasonable and necessary for the beneficiary. Third, the beneficiary must require tube feeding to maintain weight and strength commensurate with his or her overall health status. In these instances, Medicare Part B covers claims for enteral nutrition, along with the supplies and equipment necessary for administration (i.e., infusion pumps, intravenous poles, feeding supply kits and tubing).

Disregarding the qualifications and experience of a supplier of enteral nutrition therapy could lead to health complications and unintended consequences for beneficiaries. Many SNF suppliers have dieticians and clinical nursing consultants on staff. Typically, the enteral products are standardized to SNF residents based upon each SNF's specific clinical protocol. As currently devised, the competitive bidding program allows suppliers with no previous experience or familiarity with institutional settings or the enteral nutrition product category to service SNFs. SNF patients are at risk of developing subsequent illnesses - requiring a more expensive form of care - if their nutritional status and food security diminish.

Given the complexities involved with the SNF provider setting and the enteral product category, CMS stated in its 2004 Report to Congress on the 1999-2002 Florida and Texas competitive bidding pilot demonstration projects that enteral nutrition therapy *"was not well-suited for a competitive acquisition program."* The agency recommended that the product category be excluded from future rounds of competitive bidding. Given this recommendation and the fact that the SNF setting was not the intended target of competitive bidding, we question why the agency chose to include enteral nutrition therapy in both the first and second rounds of the program.

Thank you for reviewing our concerns and considering our comments. We appreciate the opportunity to suggest important modifications to the competitive bidding program that should be implemented to ensure that patients and providers continue to have uninterrupted access to life-sustaining medical products.

Independent Medical Supply Inc

Independent Medical Supply Inc.
185 E. Indiantown Road #106
Jupiter, Fl. 33477-5071
(5621)744-9074
ind_medical@att.net

5/8/12

Dear Representatives,

I am the owner of a family owned and operated medical supply store located in Jupiter Fl. We have serviced our community for 24 year's. We are located in the current Competitive Bid 1 area. I have written you to request your support in the introduced Market Pricing Program proposed to negate the CB1 and CB2 program for Medicare reimbursements of medical supplies.

As Medicare continues to tout all the positive savings in the current program they fail to acknowledge the lack of transparency and unfairness of the program. It is not unusual for us to deal with its deficiencies on a daily basis. I receive calls from as far away as Miami (90 miles) with requests for help because Medicare patients are doing without medical supplies they need or are paying for supplies out of pocket in order to receive them. For many this is a burden they can't afford. Many do without or reuse the supplies they need. This can lead to greater medical costs and physical harm to the patient. Many elderly do not complain to the very people that are able to correct the problems of the system. They are intimidated by the aspect of contacting their representatives or spending a large amount of time on the telephone with Medicare only to be shuffled along without any resolution offered by Medicare to their problems. This gives the false impression of fewer complaints than are a true representation of the program. We are the first line of contact for them to voice their frustrations and concerns yet Medicare refuses to listen or acknowledge our voices when contacted about these problems. Medicare's saving is on the backs of our seniors and medically needy.

The original CB1 Program was changed due to the unfairness of the program only to be replaced with a program just as, if not more flawed then the first. This unfairness is true for both patients and suppliers. Many of us have been forced to send our long time community patients to suppliers located at longer distances for them or their caregivers to travel.

Many of the contracted suppliers have refused to supply products due to such low reimbursement amounts or are not even located in the areas they bid let alone the same state. Many local suppliers like myself were excluded from being able to compete because of system failures rather than anything created by the supplier. Even more have had to shut their doors because of this flawed system.

Please investigate these flaws not by Medicare's account of how well it is doing but by the people who are forced to follow them. Only then will be able to correct and create a system that will serve the very people who have contributed to the Medicare fund, be transparent for the companies forced to obey them and be able to utilize Medicare's resources to its fullest without unnecessary waste.

Thank you for your time and interest in these matters,

Sincerely,
Sherrill B. Miller

Jersey Association of Medical Equipment Services

JAMES
Keeping Members Informed

Comments for the Record
From the
Jersey Association of Medical Equipment Services (JAMES)
On behalf of its Members

In Support of Hearing by the House Ways and Means Sub-Committee on Health
Held
Wednesday, May 9, 2012 at 9:00 am

Summary Statement

Chairman Herger, Ranking Member Stark, members of the Committee, the Jersey Association of Medical Equipment Services (JAMES) submits the following comments for the record regarding the hearing by your subcommittee on the flawed competitive bidding program for durable medical equipment, prosthetics, orthotics, and suppliers (DMEPOS). We are a trade association representing and supporting the durable medical equipment (DME) supplier community of New Jersey.

Our membership has raised serious concerns with the program for several years with our legislators, and has solicited their support as co-sponsors on legislation that would repeal the flawed bidding program. H.R. 1041, the Fairness in Medicare Bidding Act (FIMBA) has the support of six New Jersey House members.

New Jersey is significantly impacted by the competitive bidding program, as we have 17 out of 21 counties divided up amongst the four competitive bid area's (CBA's) that encompass the state. Two of the four CBA's cross state lines and force New Jersey DMEPOS suppliers to commit to doing business in Pennsylvania, Delaware and Maryland, if they are awarded a contract.

One of the most critical issues with competitive bidding is the apathetic lack of understanding of how the DME industry connects with other healthcare providers and functions. The DME supplier community is made up of providers who serve a local service area, sometimes as small as a few miles in any area. The bidding process of requiring a bid winner to serve the entire CBA is in itself exclusionary. An accredited provider serving the southern part of New Jersey would find it physically impossible to serve the portion of Maryland included in the CBA in a timely manner. Expecting that same supplier to subcontract in order to stay in business would require business expertise far beyond the abilities of most small businesses.

The first real challenges our members faced with the competitive bidding program occurred last August when the Centers for Medicare & Medicaid Services (CMS) announced the Round 2 specific zip codes and product categories. Suppliers located in the southern portion of

the state received confirmation that if they wanted to submit a bid to potentially continue to service their share of New Jersey's 1.4 million Medicare beneficiaries, they would need to plan to expand their operations to service areas in Pennsylvania, Delaware and Maryland. Their first commitment to this potential expansion was one that posed significant regulatory burden as they prepared their businesses for interstate commerce in a healthcare-related industry. The web of state regulations for DME suppliers varied by state; numerous licensing boards and regulatory agencies gave conflicting information, and the licensing resource provided by CMS was one that changed frequently without notice to DME suppliers. Complex out-of-state license application requirements and processing timeframes led JAMES to request relief from our legislators, and ultimately, CMS acknowledged challenges existed related to regulatory licensure requirements and granted a licensure delay.

Similar barriers to access did not apply to DME companies outside of New Jersey, as our licensing requirements are minimal. The program, as currently designed, allows a DME supplier to bid to service a CBA without the need for a physical presence in the CBA. It is possible, based on the results the industry saw from Round 1, that many New Jersey DME companies were not only submitting bids to compete against established companies in their current marketplace, but also unknown out-of-state DME suppliers. Our association office fielded many calls from DME suppliers throughout the country inquiring about the restrictive nature of the regulations enacted by our State Board of Respiratory Care. These companies were ultimately working to devise a plan to circumvent the true intent of our regulations by utilizing minimal efforts to show compliance, if awarded a contract for oxygen and CPAP product categories. Considering our regulations set forth by the State Board of Respiratory Care are based on patient safety, this has raised significant concerns for our members.

While attending a recent legislative event in the state, our association's representative had the opportunity to speak with many New Jersey small business owners. It is apparent that our small business base is still struggling to overcome the economic challenges of past years, and the competitive bidding program, as currently designed will provide additional challenges. A study conducted on potential supplier closure and job loss in the CBA's that impact New Jersey reveal there is a potential for the loss of 1,483 suppliers and 14, 831 jobs.[1] Medicare beneficiaries will experience access delays due to the magnitude of the dismantling of the New Jersey DME industry.

Unsustainable reimbursement rates, based on Round 1 outcomes, will further plague the DME suppliers who are successful at winning contracts. A recent study released discusses how lower medical equipment reimbursements have lead to the quality of such products degrading to the point where the patient is impacted by lesser-quality devices. While we are supportive of fiscal responsibility to protect the longevity of the Medicare program, we believe there are alternative ways to reflect updated pricing structures that will produce cost-savings for the Medicare program. It should be noted that CMS has ample authority to adjust prices to meet market demands without implementing such a devastating program. The concept of this misguided program came about because the creators did not understand the DME industry and how the network of over 100,000 suppliers has been woven into the fabric of healthcare in virtually every community. The businesses, small and large, live and work in neighborhoods where it is literally, "neighbors serving neighbors". It is not possible to move away from that

[1] The VGM Group. DME Competitive Bidding Will Cost More Than 100,000 Jobs. Informational brochure, 2010.

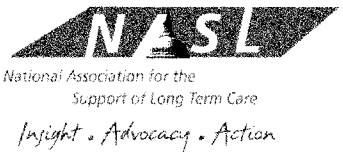
concept without harming everyone involved, including the patient, the physician, and every other component of healthcare that touches that patient.

Recent announcements by the Department of Health and Human Services regarding the finalization of the Community First Choice rule indicate the agency is committed to keeping patients in their home environment – a true cost-savings measure. We applaud this initiative, but at the same time exercise caution as we are concerned that the competitive bidding program will eliminate the very infrastructure needed to support the Community First Choice option.

As New Jersey DME suppliers await the remainder of events in the Round 2 competitive bidding timeline, our association is very concerned about competitive bidding and will work with our members of Congress to help meet the stated goals for this program following repeal. JAMES can offer alternatives that will both reduce fraud and abuse, and reduce program costs by applying realistic solutions.

Wendy Russalesi
Executive Director

National Association for the Support of Long Term Care



STATEMENT OF THE

NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE (NASL)

HEARING ON THE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) COMPETITIVE BIDDING PROGRAM

SUBCOMMITTEE ON HEALTH
COMMITTEE ON WAYS AND MEANS
UNITED STATES HOUSE OF REPRESENTATIVES

WEDNESDAY, MAY 9, 2012

The National Association for the Support of Long Term Care (NASL) submits this statement to the House Ways & Means Subcommittee on Health for its May 9, 2012 hearing on the Medicare Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program.

NASL represents providers and suppliers of products, medical supplies, diagnostic testing, professional services, therapy, and information systems for the long-term and post-acute care (LTPAC) industry, as well as LTPAC providers. NASL members include suppliers and manufacturers of durable medical equipment, prosthetics, orthotics and enteral nutrition, providers of physical, occupational, respiratory and speech-language pathology therapies, and health information systems developers.

Simply stated, NASL remains concerned that the Medicare competitive bidding program needlessly forces quality suppliers out of the Medicare program. It is poorly structured and, we believe, ultimately is destined to fail, thus creating serious access and quality issues for Medicare beneficiaries in need of DMEPOS products and services. Briefly, our principal concerns are the following:

- Under the current competitive bidding system, 50% of the "winning" bidders must accept payment levels that are below their bids, which is directly contrary to the basic rules of competitive bidding programs conducted elsewhere in the federal government. Thus, the Centers for Medicare & Medicaid Services' (CMS') competitive bidding program does not accurately reflect the market for a particular product category in a particular geographic area. Despite the description of the program as market-based, it really is nothing more than an arbitrary fee schedule that is applied to a reduced number of participating DMEPOS suppliers.
- The combination of allowing non-binding bids and inviting inexperienced suppliers to bid for the contracts has resulted in further distortions of the market, which is only accentuated when some of the lowest bidders walked away from the program but their bids still influenced the competitive bidding payment amounts.
- CMS has not made public the level of information necessary to gauge how successful the competitive bidding program really is in terms of patient access to quality care. For example, CMS has not responded

> to the request of the Program Advisory and Oversight Committee (PAOC) for information in 2011 that would enable the PAOC to assess the impact of the competitive bidding program on beneficiaries and suppliers. Preliminary analyses performed by outside economists have at least raised the question that the reduction in utilization of DMEPOS products and services in the competitive bidding areas may be adversely affecting Medicare beneficiaries' access to medically necessary care. Round Two of the program, which is a ten-fold increase in the scope of the competitive bidding program, should not be undertaken until CMS demonstrates that patient access to care has not been compromised.

In addition to these basic concerns that are shared by virtually all DMEPOS suppliers, NASL wishes to raise particular issues that result from the application of the competitive bidding program to products provided in nursing facilities. One of the product categories that was included in Round One and expected to be in Round Two of the competitive bidding program, enteral nutrition, is primarily provided to residents of nursing facilities. This presents issues that go far beyond the scope of the competitive bidding program, as explained below.

Enteral nutrition involves the provision of nutrients by tube into a patient's stomach or intestine. It is prescribed by physicians for patients whose lower gastrointestinal tract functions normally but who are unable to swallow, who have a gastric obstruction or who cannot otherwise ingest adequate amounts of food and fluids by mouth. Medicare Part B covers enteral nutrition formulas, supplies and equipment under the prosthetic device benefit when enteral nutrition is necessary for the patient to maintain weight and strength commensurate with his or her general condition.

It is noteworthy that enteral nutrition was not tested successfully during the two demonstration projects that preceded the enactment of the Medicare Modernization Act of 2003, which created the competitive bidding program for DMEPOS items and services. In fact, enteral nutrition was removed from the Polk County, Florida demonstration, in large part, we believe, because most enteral patients in that county resided in nursing facilities. This created complications that CMS did not want to address at that time.

Nursing facilities have a special relationship with their residents. In most instances, the nursing facility is the resident's home. The nursing facilities

are responsible for providing complex nursing and rehabilitative therapy services involving an array of clinicians, providers and suppliers to meet patient health care needs, and the facilities are held accountable for the quality of these services. Nursing facilities must meet detailed conditions of participation to participate in the Medicare and Medicaid programs as well as a wide array of additional federal and state requirements regarding patient safety and quality of care. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, and suppliers understanding of the fragile and medically complex patient that relies on the nursing facility for care.

For these reasons, many nursing facilities were extremely concerned that the competitive bidding program would force them to admit unfamiliar suppliers into their facilities to provide services, supplies and equipment to their residents. NASL agrees with nursing facilities on this point – that the facilities must be able to select the suppliers that the facilities believe can best enable them to meet resident needs and comply with applicable standards. Unfortunately, the competitive bidding program has interfered with their ability to make these decisions regarding the enteral nutrition needs of their residents, and has disrupted ongoing relationships that had worked to the benefit of their residents. The fact that grandfathering (i.e., permitting non-winning bidders to continue to provide care to their current patients if they accept the competitively bid rates) was not extended to enteral nutrition ensured that every nursing facility that did not win a bid, or where the particular nursing facility's enteral nutrition supplier did not win the bid, had to find a new enteral nutrition supplier.

In addition, the provision of enteral nutrition therapy in nursing facilities differs from the provision of therapy in patients' homes. Residents in nursing facilities often are more impaired than home care patients and require a different regimen of care. Enteral patients in nursing facilities have dietary needs that change more frequently than most home care patients, thus requiring an enteral nutrition supplier that can readily address their special needs. An enteral supplier that has had no experience working with the complex medical needs of nursing facility residents may not be an adequate replacement for a supplier that has had years of such experience.

We do not believe there has been adequate scrutiny of the application of the competitive bidding program to nursing facility residents. We urge

Congress to require CMS to provide the data to the Government Accountability Office for its required analysis of the competitive bidding program, and the public, to address the following issues:

- Changes in treatment patterns of enteral nutrition patients in nursing facilities in competitive bidding areas, and whether the use of new enteral nutrition suppliers has increased nursing facility costs for the care of their enteral nutrition patients;
- Observations from nursing facilities' clinicians as to any diminution in quality of enteral nutrition therapy provided to their residents;
- Incidence of re-hospitalization of nursing facility residents in need of enteral nutrition in competitive bidding areas in 2011, compared to the re-hospitalization rates in those areas in 2010; and
- Whether the new enteral nutrition suppliers providing enteral nutrition to nursing facility residents had previous experience in treating nursing facility residents.

In addition, we request that Congress require CMS to grandfather all patients and products involved in the competitive bidding program in any future expansion or extension of the program.

Additional Recommendations

We join with numerous other commenters in advocating for the adoption of the concept of the Market Pricing Program developed by the DMEPOS industry. We believe that better definitions of the professional services and related costs for the provision of DMEPOS, along with a fairer and more reasonable bidding regimen that will accurately capture market prices, will be a dramatic improvement over the current competitive bidding program.

If Congress decides to continue with the current competitive bidding program, then we urge Congress to correct the deficiencies in the program we have identified in this statement. In addition, we urge Congress to modify the planned product categories for the Round One Re-Compete, scheduled to go into effect in 2014 for the original nine competitive bidding areas. CMS intends to group certain unrelated product categories into larger categories. For example, CMS intends to create a new "General Home Equipment and Related Supplies and Accessories" category that will encompass hospital beds and related accessories, group 1 and 2 support services, transcutaneous electrical nerve stimulation devices, commode

chairs, patient lifts and seat lifts. Many suppliers provide some but not all of these items. As a result, this will lead to several disturbing problems:

- This approach unfairly favors large, "one-stop shop" operations, which ultimately will be anti-competitive.
- Specialty or niche suppliers that have significant experience and enviable track records for quality for one or several of the items will be at a distinct disadvantage in the bidding for all of the items in this category.
- To survive in this bidding process, small or niche suppliers will have to increase the degree of subcontracting to cover the wide array of products in the category. Subcontracting increases the possibility of patient and provider confusion, disruptions in care and similar issues.
- For those suppliers that choose not to subcontract to provide the full array of items in this category, they must attempt to become proficient and efficient in product areas with which they do not have experience. We believe the Medicare program should be providing incentives to suppliers to provide services and products in areas where they excel, instead of encouraging suppliers to experiment in other product areas.

The DMEPOS competitive bidding program must be designed to still produce savings for the Medicare program, and not diminish the quality of products, supplies and services for the patient. Therefore, we thank the committee for bringing attention to the issue by holding this hearing and urge Congress to complete a full analysis of the competitive bidding program before it expands the program to 91 Metropolitan Statistical Areas. NASL, is an organization that represents suppliers and manufacturers of durable medical equipment, prosthetics, orthotics and enteral nutrition, stands ready to be a resource, as you carry out the important work relating to the competitive bidding program.

National Association of Chain Drug Stores

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

U.S. House of Representatives
Ways and Means Committee
Subcommittee on Health

Hearing on:

The Medicare Durable Medical Equipment
Competitive Bidding Program

May 9, 2012
9:00 a.m.
1100 Longworth House Office Building

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The National Association of Chain Drug Stores (NACDS) thanks the Members of the Subcommittee on Health for consideration of our statement for the hearing on "The Medicare Durable Medical Equipment Competitive Bidding Program" to understand how the program is impacting patients, suppliers and program expenditures.

In 2003, Congress created the Medicare Part B competitive bidding program for durable medical equipment (DME). While diabetes testing supplies (DTS) are considered DME under the Medicare program, the Centers for Medicare & Medicaid Services (CMS) has intentionally and wisely excluded diabetes testing supplies furnished by retail pharmacies from competitive bidding, thereby ensuring beneficiary access to these vital supplies. Without this exclusion, it is highly unlikely that retail pharmacies would be able to furnish DTS in Medicare, since competitive bidding reimbursement rates are below DTS product costs for retail pharmacies. Limiting access to DTS will lead to poorer health outcomes and escalating costs of care.

Early evidence suggests that beneficiaries requiring diabetes testing supplies and living in a competitive bidding area under Round One of the program have actually shifted towards obtaining their DTS from their local community pharmacy. If this is the case it would indicate that mail order providers participating in the program are unable to provide the needed supply of DTS, a situation that would only become increasingly problematic should the beneficiary option to use the retail setting be eliminated. It is necessary that retail pharmacies be maintained as a safety valve for beneficiaries in competitive bidding areas. NACDS urges a comprehensive review of Round One of the Competitive Bidding Program (CBP), with a particular focus on access to DTS, including a review of beneficiary health outcomes and the ability of mail order suppliers to provide beneficiaries with their choice of supplies in the competitive bidding areas.

Chain pharmacies, which make up 66% of retail community pharmacies, are a vital access point for both diabetes testing supplies and prescription medications. Maintaining access to

diabetes testing supplies at local pharmacies allows seniors to access all of the equipment and prescription drugs they need to manage their disease from a single source.

Pharmacists are uniquely qualified as medication experts to work with patients needing medical supplies such as diabetes testing supplies. Pharmacists play a key role in ensuring patients use their supplies in the most proper and meaningful way. Including retail pharmacies in the competitive bidding program will limit the number of options available to beneficiaries. This will also prevent some beneficiaries from continuing the relationship with pharmacists they have been using for years. Beneficiaries should have the continued ability to obtain their medical supplies from pharmacies with which they have a long-standing relationship.

One-on-one patient consultations provided by local pharmacists are often the first opportunity to identify other chronic illnesses and changes in patients' conditions, and these consultations often result in early detection, referral and treatment. Continued participation of community retail pharmacies in serving Medicare patients with medical supplies such as DTS should therefore be a priority of the Medicare program.

In addition to resisting moving any segment of retail pharmacy into the Medicare competitive bidding program, NACDS urges the following future actions under the Competitive Bidding Program to ensure beneficiary access to all retail locations which are critical to access and care coordination for diabetes patients:

- **Avoid proposals that reduce reimbursement for diabetes testing supplies obtained at a retail pharmacy to the level provided to mail order suppliers participating in the competitive bidding program, given that such an approach would not reflect the health-improving, cost-saving value of retail pharmacy services.**

- **Consider alternative approaches which would produce program savings without compromising beneficiary access and health, such as moving coverage of diabetes testing supplies from Medicare Part B to Part D.**

Do Not Lower Reimbursement for Retail DTS to Mail Order Levels

NACDS is concerned with proposals which would lower the reimbursement rate for diabetes testing supplies obtained at retail pharmacies to the level paid to mail order suppliers in the CBP. Such an approach does not take into consideration the added value, in terms of improved health and reduced costs that result from services provided by retail pharmacies. This reimbursement reduction would hurt access to care and severely limit the valuable role of pharmacist-patient interactions in reducing overall program spending. Such reduced access and the elimination of face-to-face pharmacist counseling will lead to under-testing, decreased medication adherence, poorer outcomes, and increased overall costs. We urge the Subcommittee to advance healthcare proposals that not only improve patient outcomes, but can be implemented in a manner that does not increase overall costs. Lowering reimbursement for retail DTS would accomplish neither of these goals.

Move DTS From Medicare Part B to Part D

The Committee should consider moving diabetes testing supplies from Medicare Part B to the Part D program. Prescription drugs related to diabetes, such as insulin, are provided to Medicare beneficiaries through Part D. However, durable medical equipment such as diabetes monitors, testing strips and lancets are provided to Medicare beneficiaries through Part B. This results in difficulties coordinating care.

Diabetes supplies should be covered through the Part D benefit. This would mirror commercial practices, would allow beneficiaries with diabetes to access necessary medications and supplies from the same provider if they chose, and would reduce costs by moving products to the more efficient Part D program, which continues to operate below Congressional Budget Office (CBO) projections. Conversely, proposals to expand the

competitive bidding program to include retail pharmacy-provided diabetes testing supplies are inherently flawed, as they fail to take into account that fragmenting care for Medicare beneficiaries with diabetes will inevitably result in increased costs.

CONCLUSION

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.

Reliable Medical Inc

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Medicare Durable Medical Equipment Competitive Bidding Program

Att: Wally Herger, Chairman
Subcommitte on Health

Our company has been servicing medicare patients for almost 7 years and we pride ourselves in our caring and efficient service to our patients.

We contracted with Agape Medical Management from Riverside. California to assist us in the submission of our bid for round 2. They came highly recommended by Invacare Supply Group. Their process is to send you specific tasks, which we completed and they would enter all the data into D Bids. The bid would be returned to us for accuracy and we would submit it to Medicare. We were bidding in 4 areas and 7 catagories.

We had trouble communicating with this company. You could not get through to anyone, all voice mails were full and no one called you back. At noon on March 30th, we spoke to Don Hudson our sales person. He assured me that we would have everything by 3P.M. EST. After that conversation we could not get through to them. Our bids were never entered and we were unable to get into D Bids. When the CBA's started to populate, we were only able to complete 2 oxygen CBA's, which I am sure you can see. We called Agape first thing Monday morning only to be told they were closed. On Tuesday, April 3rd, we were told that everyone was on vacation until April 9th.

We have since been in touch with many companies who are in the same position as we are. We contacted Elaine Hensley from Palmetto. She said she would forward our information to Medicare. Cara Bachenheimer from Invacare advised us to contact John Blum and Laurence Wilson from Medicare.

Agape told us that the computers were so overloaded that they could not complete the data entry. It seems that they were trying to lower the playing field and if less people submitted bids, the remaining companies would have a better chance. I don't know the statistics from Round 1 but I am sure some companies who did not get the bid went out of business. I am sure this will happen with round 2.

All we want is a chance to enter our bid.

This whole process cost a fortune to implement. You would have been better off just cutting the reimbursements . Having less companies service these patients will also affect the quality of care given to medicare patients.

Smith and Nephew Inc

Written Testimony Submitted to the United States House of Representatives
House Ways and Means Health Subcommittee
1100 Longworth House Office Building
May 9, 2012 Hearing on the Medicare Durable Medical Equipment Competitive Bidding Program

On Behalf of Smith & Nephew, Inc.
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Chairman Herger, Ranking Member Stark and Members of the Subcommittee, on behalf of Smith & Nephew, Inc., I would like to thank you for holding this important hearing on Medicare's Durable Medical Equipment competitive bidding program.

Smith & Nephew is a global medical technology business dedicated to helping improve people's lives. With leadership positions in Orthopedic Reconstruction, Advanced Wound Management, Sports Medicine, Trauma and Clinical Therapies, the Company has almost 11,000 employees and a presence in more than 90 countries, including more than 4,000 employees in the United States. Annual sales in 2011 were nearly $4.3 billion.

Smith & Nephew's Advanced Wound Management division makes a wide range of products designed to help the healing process and improve patient quality of life. These include advanced films, foams and polymeric gels that create a moist environment that encourages healing, and antimicrobial dressings and ointments for treating and preventing wound infection. Potential benefits to patients include fewer reapplications of dressings, less discomfort and pain, faster healing and reduced risk of complications. Treatment is clinically effective, less time-consuming and contributes to improved outcomes, and is therefore more cost-effective.

Each year, Smith & Nephew trains thousands of healthcare professionals, offering programs and seminars from classroom to bedside. Smith & Nephew's research and development team is committed to helping people regain their lives and continues to advance wound care solutions that help reduce the human and economic costs of wounds.

Some of these products, in particular negative pressure wound therapy (NPWT), are paid for by Medicare as durable medical equipment (DME). NPWT is one of the DME categories under Round 2 of the competitive bidding program.

The benefits of NPWT are the result of multiple mechanisms of action. When the therapy is applied, a pressure gradient is created and results in physical forces being applied to the wound, removal of edema, improved blood flow, and removal of bacteria and wound fluid. The combination of these mechanisms stimulates the generation of new tissue and promotes wound healing. NPWT is a vital tool for doctors and wound care specialists. Multiple clinical studies provide the evidence that NPWT helps patients heal faster with a reduced risk of infections and complications.

Our testimony before the Subcommittee today focuses on two issues. First, we wish to express our strong support for the concept of the DME competitive bidding program as a tool to encourage market-based reimbursement while ensuring Medicare patient access to home medical equipment from an ample network of qualified suppliers. In particular, we have some comments related to the Market Pricing Program (MPP), which has the support of the American Association of Homecare, multiple economists and auction experts from around the world.

We understand that Subcommittee has heard multiple stakeholders describe the various bidding methodologies, but we believe the MPP more appropriately and transparently arrives at competitive bids and ensures only legitimate suppliers participate.

I will not restate the details that the Subcommittee already has received from other stakeholders; but as a company deeply impacted by the competitive bidding process, it is our experience that Medicare patients benefit only when qualified bidders provide products in a financially sustainable bidding program. We firmly believe that the MPP proposal developed by the independent auction experts should receive serious consideration by both Congress and the Centers for Medicare and Medicaid Services (CMS).

Second, we commend CMS for the agency's interpretive guidelines for CMS-approved accrediting organizations. These entities will use the guidelines in accrediting suppliers that provide NPWT equipment to Medicare beneficiaries. The guidelines provide important patient safety protections, including specifications for suppliers to coordinate with the prescribing physician to confirm orders, ensure equipment delivery with home health care providers, and perform all needed quality checks on the various NPWT components. These final interpretive guidelines are a culmination of discussions among NPWT manufacturers, industry associations, and CMS. We applaud CMS's leadership in bringing this process to a close.

In addition, CMS has provided assurances that the agency will track patient access to and outcomes from NPWT, in both competitive bidding and non-competitive bidding areas, to enable the agency to assess the effectiveness of the program following implementation. We believe this will allow stakeholders to assess whether modifications are needed due to Medicare patient access concerns. We appreciate CMS's commitment to monitoring the impact of the program.

Conclusion

Smith & Nephew, Inc., is confident that the competitive bidding process can be successfully implemented on a broad scale, and we urge the Subcommittee to seriously consider MPP as a means to establish market-based prices around the country. We believe that an appropriate bidding methodology and strong guidelines for accrediting organizations will ensure that only qualified NPWT suppliers win bids. This will achieve Medicare cost savings while ensuring appropriate access to care for Medicare beneficiaries.

We appreciate the work of the Subcommittee and the efforts of CMS to implement a program that lowers costs, maintains access to DME products for Medicare beneficiaries, and uses bidding methods attracting only legitimate suppliers. We look forward to working with this Subcommittee and all Members of Congress as the Medicare competitive bidding program is further implemented.

Questions? Please contact:

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T2United Spinal Association

Expanding Opportunities for Veterans and All Paralyzed Americans

House Ways and Means Health Subcommittee
May 9, 2012

Impact of the DMEPOS competitive bidding program on beneficiaries, suppliers, and Medicare expenditures and the implications for program expansion

Statement for the Record of Paul Tobin
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Introduction

My name is Paul Tobin and I am President and Chief Executive Officer of the United Spinal Association. I previously served as the Association's deputy executive director and was a member if its Board of Directors from 1995 to 1996. I have also held a variety of other managerial positions at the Association including hospital services officer, director of special projects, and group director of benefit services. I earned my Bachelor of Science degree in civil engineering in 1991 from Manhattan College. I later attended the U.S. Navy Officer Candidate School in Newport, RI, from which I was commissioned an ensign and joined the Civil Engineering Corps. After sustaining a spinal cord injury in August 1993, I underwent rehabilitation at the Castle Point Veterans Affairs Medical Center in New York. I have since earned a Master degree in Social Work at Fordham University and am taking coursework for a Master degree in Public Health Administration at Columbia University. My statement focuses on the impact the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program has on the spinal cord injuries and disorders community.

United Spinal Association is a national non-profit organization founded by paralyzed veterans in 1946 and headquartered in New York. United Spinal has since provided service programs and advocacy to improve the quality of life of individuals with disabilities across the life span living with spinal cord injuries and disorders (SCI/D) such as multiple sclerosis, amyotrophic lateral sclerosis, post-polio syndrome and spina bifida. There are more than a million individuals throughout the country with SCI/D and to whom the Association's work is dedicated. United Spinal has more than 35,000 members and 68 chapters and support groups nationwide. Throughout its history, United Spinal Association has devoted its energies, talents and programs to improving the quality of life for these Americans and for advancing their independence. United Spinal Association is also a VA-authorized veterans service organization serving veterans with disabilities of all kinds.

Consumer Access to Quality Products and Services

Individuals with disabilities rely on access to quality products and services that enable us to be contributing members of society by being employed and active in our communities. Access to the right products and services fosters our independence and equality in the pursuit of happy productive lives and dreams.

United Spinal Association has been monitoring the Medicare DMEPOS competitive bidding program through the roll-out and implementation of the initial Round One that occurred in July 2008 through today. The Round One Rebid went into effect last January for nine areas across the country: Cincinnati and Cleveland, Ohio; Charlotte, North Carolina; Dallas, Texas; Kansas City in Kansas and Missouri; Miami and Orlando in Florida; Pittsburgh, Pennsylvania and Riverside, California. United Spinal has heard numerous complaints from beneficiaries regarding the Round one Rebid and its impacts on their preferred equipment and services from their trusted providers. Some have had difficulty finding a local equipment or service provider. Others have experienced delays in obtaining medically required equipment and services or longer than necessary hospital stays due to equipment delays before discharging patients to home-based care. Others have bemoaned their fewer choices when selecting equipment or providers and the loss of

one-stop shopping and the quality of services. They also pointed out the confusing or incorrect information Medicare provided to them about the changes while others felt totally ill-prepared. The lessons from the Round One Rebid raise serious concerns about what will result in Round Two next July when 91 additional areas will be affected across the west, midwest, south and highly populated northeast regions of the United States. Cities included in Round Two include the highly populated Chicago, Los Angeles and New York competitive bidding areas (CBAs) all of which had to be subdivided into multiple CBAs. As a New York resident, I am concerned about the impact on consumer access in the New York CBA which is divided into 5 subcategories and includes New Jersey and Pennsylvania. The subdivisions are: Bronx-Manhattan, NY; Nassau-Brooklyn-Queens, NY; northwest NYC metro, NJ; northern NYC metro, NY; southern NY metro, NY-NJ; and, Suffolk County, NY. I can personally speak to the hours that I spend stuck in traffic getting from point A to point B and this is a concern for me and others within the disability community that rely on their durable medical equipment providers and their assistive technology professionals to reach them in a timely manner. A consumer in the Miami CBA informed us that she cannot move independently within her own house and had to travel 60 miles to Miami to have her wheelchair fixed because there were no contract providers in her immediate area. Additionally, consumer access is affected by the competitive bidding program by the fact that small businesses may be unable to withstand the pricing model, leaving fewer suppliers in the marketplace from which consumers can obtain needed equipment and services over time, this will result in higher prices for the consumer service resulting in higher prices for the consumer and larger companies consuming more of the marketplace.

For the Round One Rebid, 356 suppliers were awarded contracts to provide durable medical equipment and supplies, including Standard (Power and Manual) Wheelchairs, Scooters, and Related Accessories to Medicare beneficiaries in the 9 Round One Rebid competitive bidding areas. Of the estimated 47 million Medicare beneficiaries, about 2 million beneficiaries that are dependent on the competitive bidding program for coverage of products and services reside in the nine competitive bidding areas.[1] United Spinal Association will be sure to monitor closely the number of contract suppliers that are available to Medicare beneficiaries with disabilities under Round Two of the program in 91 additional areas.

Of 127,466 inquiries in 2011 that CMS claims it received, only 151 were classified as complaints. CMS states that their pre- and post- implementation beneficiary satisfaction survey did not reveal systemic beneficiary access or satisfaction problems with the competitive bidding program. The agency also tracked health outcomes, including hospitalizations, physician visits and deaths for beneficiaries potentially affected by the program. However. the data that needs to be analyzed are the same consumer population sets pre- and post- bidding and health outcomes data over the long-term looking at how that population is being impacted. Moreover, when is an inquiry an inquiry versus a formal complaint? If a consumer inquires with CMS about why they are having difficulties under the new program finding needed equipment and services, should that not be registered as a complaint?

Recently, CMS' Actuary Office found that Round 1 has reduced program expenditures by $202 million in 2011. CMS expects the competitive bidding program to save $43 billion over the next

[1] GAO Report, 'Medicare: Review of The First Year of CMS' Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid', p.3.

10 years, including saving beneficiaries $17 billion, referring to beneficiary co-pays. However, these numbers do not take into consideration the health outcomes data of Medicare beneficiaries over the long-term or the increase in insurance premiums. Individuals with disabilities who are on Medicare, in many cases, do not call the federal government when a problem arises with their equipment or services. Most consumers are concerned they might lose their government benefits and are more likely to call their supplier or a family member or caregiver for assistance.

Another concern that I have is the implementation of the national mail-order program next July due to the high incidence of diabetes within the SCI community. According to Dr. Jerome Stenehjem, medical director of the Sharp Rehabilitation Center, San Diego, California, "[p]eople with spinal cord disorders are more prone than most to developing type 2 diabetes." A recent survey published in the Journal of Spinal Cord Medicine states that overall prevalence of diabetes in individuals with an SCI/D was 20% (3 times higher than in the general population).[2] United Spinal Association will continue to monitor closely the impact that the competitive bidding program has on the SCI/D community.

A report published in May by the American Journal of Physical Medicine and Rehabilitation found that over 50 percent of wheelchair users experienced a breakdown in a six-month period. "It is possible that this increase in the number of repairs is the result of a decrease in wheelchair quality resulting from changes in reimbursement policies ....." write the researchers, led by Dr Michael Boninger of University of Pittsburgh's Department of Physical Medicine and Rehabilitation. They also found a significant increase in wheelchair breakdowns causing health and safety consequences.[3]

Consumer Education

Medicare needs to continue to work at educating the consumer about how best to find a supplier and what a grandfathered supplier is. CMS admits that the Round One Rebid did not start cleanly relative to information accuracy on the CMS website about contract suppliers and what products they provided to beneficiaries. United Spinal looks forward to seeing an improved roll-out for Round Two where far more beneficiaries will be affected. I would also like to draw attention to the wheelchair repair and replacement regulations. Permanent residents within a CBA are required to obtain replacement of all items subject to competitive bidding from a contract supplier, including replacement of base equipment and the replacement of parts or accessories for base equipment that is being replaced for reasons other than servicing of the base equipment (such as the need for a different piece of equipment due to the beneficiary's weight or equipment usage). Without a strong education initiative, beneficiaries in need of wheelchair repair and replacement may face significant access challenges to appropriate equipment and services.

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[2] J Spinal Cord Med. 2006; 29(4): 387–395. "Diabetes Mellitus in Individuals With Spinal Cord Injury or Disorder"

[3] Am J Phys Med Rehabil 2012;91:00Y00. "Increases in Wheelchair Breakdowns, Repairs, and Adverse Consequences for People with Traumatic Spinal Cord Injury"

CONCLUSION

On behalf of the more than one million individuals throughout the country with SCI/D (spinal cord injuries and disorders) such as multiple sclerosis, amyotrophic lateral sclerosis, post-polio syndrome and spina bifida, I urge this committee to look closely at how the Centers for Medicare and Medicaid Services is gathering data on the impact this program has on all consumers, including people with disabilities and United Spinal Association will continue to monitor how the program is impacting consumers. As the Government Accountability Office noted in its testimony:

Although the first year of the CBP round 1 rebid has been completed, it is too soon to determine its full effects on Medicare beneficiaries and DME suppliers. Although we found that the round 1 rebid was, in general, successfully implemented, our findings are based on the limited data available at the time we did our study and for only the first year of the rebid's contract period. While the prevalence of grandfathered suppliers for some CBP rental items may have ameliorated beneficiary access concerns during the first year, the number of grandfathered suppliers will continue to decrease as rental agreements expire. Likewise, it is not yet known whether any change in the number of subcontracting suppliers will affect beneficiary access....it is important to continue to monitor changes in the number of suppliers serving CBP-covered beneficiaries and trends in utilization of the CBP-covered DME.[4]

[4] GAO Testimony, 'Medicare: The First Year of the Durable Medical Equipment Competitive Bidding Program Round 1 Rebid', p.6.