MEDICARE'S DMEPOS COMPETITIVE BIDDING PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

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

ONE HUNDRED TENTH CONGRESS

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MEDICARE'S DMEPOS COMPETITIVE BIDDING PROGRAM

TUESDAY, MAY 6, 2008

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

The Subcommittee met, pursuant to notice, at 1:00 p.m. in room 1100, Longworth House Office Building; Hon. Fortney Pete Stark (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
April 29, 2008
HL–24

CONTACT: (202) 225–3943

Hearing on Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program

House Ways and Means Health Subcommittee Chairman Pete Stark (D–CA) announced today that the Subcommittee on Health will hold a hearing on the DMEPOS Competitive Bidding Program. The hearing will take place at 1:00 p.m. on Tuesday, May 6, 2008, in the main committee hearing room, 1100 Longworth House Office Building. In view of the limited time available to hear 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.

BACKGROUND:

Currently, Medicare payment rates for most types of medical equipment and supplies are based on fee schedules. The Medicare Modernization Act of 2003 (MMA) required that the Centers for Medicare & Medicaid Services (CMS) use a competitive bidding process to contract with suppliers and other providers for certain types of equipment and supplies. The Competitive Bidding Program will be phased in over time, starting with 10 of the largest Metropolitan Statistical Areas (MSAs) in 2008 and expanded into another 70 MSAs—including New York, Chicago, and Los Angeles—in 2009. MMA gives CMS the authority to expand the program beyond those 80 areas starting in 2010 and allows the agency to adjust DMEPOS payment rates in areas of the country that do not fall under the Competitive Bidding Program.

In early May, CMS announced preliminary results of the first round of the bidding program. Based on contract offers, payment rates will be reduced by an average of 26 percent in the ten areas covered by round one. However, concerns have been raised that some suppliers were improperly excluded from the bidding process and beneficiary access to certain types of equipment could be reduced in areas affected by the program.

In announcing the hearing Chairman Stark said, **"We have heard from both suppliers and beneficiary advocates that the DMEPOS competitive bidding program is not working as well as it is supposed to. I look forward to hearing their concerns, as well as from CMS, as we consider whether changes need to be made before the program is further expanded."**

FOCUS OF THE HEARING:

The hearing will focus on implementation of the administration of Medicare's DMEPOS Competitive Bidding Program.

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 "110th Congress" from the menu entitled, "Committee Hearings" (*http://waysandmeans.house.gov/Hearings.asp?congress=18*). 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." Follow the online instructions, completing all informational forms and clicking "submit". Attach your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **Tuesday, May 20, 2008**. 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.

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 or WordPerfect 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.

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

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.

Chairman STARK. I apologize to our witnesses and guests, but Health and Human Services has been calling procedural votes on the floor of the House in an effort to prevent this hearing from going forward. We're pleased that we're here at any rate to review the development and execution of the "Durable Medical Equipment Competitive Bidding Program" mandated in MMA of 2003, and the program was to be phased-in over time. It started in ten of the largest metropolitan areas already and scheduled to move rapidly to another 70 areas in 2009 and may then be taken nationwide.

While durable medical expenditures are a very small part of the overall Medicare spending, we think about 2 percent, all of us are well aware the changes to this benefit will have a significant impact on suppliers and beneficiaries in each of our districts all over the country. Spending has been growing rapidly in this area, and that provides good cause for review of how we pay for durable medical equipment.

This hearing was called because of the concern from colleagues who are hearing from the suppliers in their communities and this is something that affects every district; and, as this change would, it's vital that we perform oversight. We've learned, so far, not much from this program. CMS will update us on their thoughts in a few minutes, but there are a few points that I'd make first.

The good news from this demonstration is it's apparent that companies that are willing to take Medicare's business at a far lower price than the current fee schedule rates. The estimate is that Medicare would save 26 percent over the current fee schedule.

That's a big savings. The accreditation process is also important. The DME industry has been a service industry and it's had excessive fraud and abuse, mostly because it's not very expensive to start up a line of business and there's been little oversight to ensure that the businesses are legitimate and the accreditation process is a positive step and I applaud it.

There are many questions about the process used by CMS to implement this first round demonstration. Preliminary numbers presented to the Congressional staff at a recent briefing indicate that out of 1,005 applications, 630 were rejected for lack of proper documentation.

That's more than 60 percent of the applicants. A refusal rate of that percentage does not show the market working. They weren't excluded because they failed to meet the standards, they were excluded because they didn't understand the rules or couldn't follow the directions and fill out the paperwork properly.

I will wait for CMS to provide their testimony, and we can discuss their thoughts on this first round process. At a minimum, it seems there should be strong lessons learned, and how we can do it better. If this process is going to be repeated hundreds of times around the country, my question is whether there is value added to repeating this process again and again in each and every community.

Might Medicare be better served and significant administrative costs saved by requiring all suppliers to meet the new accreditation standards and then taking what we learned in this first round to change the fee schedule by which we now pay for DME. Those improvements can be done once and will immediately be in effect nationwide. That for one idea seems simpler and much fairer and less disruptive to suppliers and beneficiaries.

We can continue this discussion after we have heard the testimony, and I would like to yield now, if I may, to the distinguished ranking Member of the full Committee for comment.

Mr. MCCRERY. Thank you, Mr. Chairman.

I wanted to come by the hearing today for a few minutes, because I think this is a very important subject. The Subcommittee and some in Congress are contemplating taking what I think would be a step that ought to be taken with great caution, because I believe that this program is outlined in legislation that we passed a few years ago does hold out some hope for hoping to control costs in this portion of the Medicare Program.

I think the Chairman just outlined very well the considerations of the Subcommittee ought to take up and examine, and I have thought about the solution that the Chairman just suggested,

which would be to require some sort of certification for all vendors of durable medical equipment and then reset the reimbursement rates for the various devices at a more appropriate level. But I think, Mr. Chairman, what we have found through the years with Medicare is that it's very difficult for us to keep pace with the reality of the market in terms of setting prices; and, inevitably we are behind the curve. I just hesitate as a single Member of the House and Member of this Committee that has jurisdiction over this matter, I hesitate to take action which would possibly threaten the existence of this new competitive bidding approach. I hope that we can arrive at some solution that gets at the particular problems that the Chairman pointed out in his opening remarks without throwing the whole thing over the side, and give it a chance to work. Let's see what happens.

I would prefer that, Mr. Chairman, to junking the whole thing and then trying to reset the prices at the appropriate level. I just think particularly in this segment of Medicare it's going to be very difficult for us to do. It seems that the pilot project is in place now and soon to be expanded to only ten regions, only ten in the whole country.

We have a chance to learn from the mistakes of this round and employ some better procedures in the next round. That's why, if the Chairman will recall we did phase-in this program slowly over time so we could learn as we go along.

So, I just wanted to come and urge the Subcommittee, Mr. Chairman, to delve into this and be very careful about actions that the Subcommittee suggests for fear in my view of jettisoning this approach before we even get a chance to see how well it works. I appreciate the Chairman letting me speak.

Chairman STARK. I'd like to associate myself with your remarks. If no other reason, we're faced with a budget dilemma. If, in fact, we cancel the program, there are projected savings of millions of dollars, and how do you get that. So, I don't think that the idea of just wiping the slate clean is an alternative and I certainly wouldn't want my remarks to be construed, and I know yours weren't. The question is what can we learn and how could the system be improved.

Mr. Camp, do you have?

Mr. CAMP. Thank you, Mr. Chairman.

Chairman STARK. Thank you.

Mr. CAMP. Well, thank you, Mr. Chairman. I thank you for convening this hearing on this issue of the competitive bidding of durable medical equipment and Medicare.

I think we need to examine Medicare's payments for these types of supplies to ensure that beneficiaries get the best quality care and the best equipment at the best price.

We have heard a number of complaints about how this program is being implemented, and I think it's important to remember however how we got here, because Medicare does use its negotiating power to administratively set prices for durable medical equipment along with a number of other goods and services that it covers. I think if there's one lesson we should all take from this situation it's that the government often does a lousy job when it comes to setting prices.

We've had a number of government audits and reports that have highlighted how Medicare was overpaying for certain types of equipment, and these reports by GAO and the HHS Inspector General compared Medicare's payments rates to other purchasers found that Medicare paid more than all other payers for certain durable medical equipment. These reports triggered the mandate by Congress for the demonstration projects to develop an alternative to the government setting prices for DME.

CMS conducted competitive bidding demonstrations in Florida and Texas and I know we'll here testimony about how that resulted in savings of nearly 20 percent overall on each site, and, obviously, the access and quality remained unchanged there. But, even though CMS has made a tremendous effort in getting this program successfully underway, there are problems. We've all heard about those problems, particularly relating to the submission of bids and questions about whether the bid winners will have the ability or the capacity to serve existing Medicare populations.

While suppliers argue these issues will limit access for beneficiaries living in certain areas and will decrease the quality of services they receive in the short term, I am concerned how these issues could ultimately reduce the number of providers that supply these items and actually increase costs in the long run. So, I believe we need a way to resolve these implementation issues as quickly as possible.

If the government continues to set inaccurate prices or fails to truly create a competitive environment, and I frankly think competitive bidding as it's currently structured is not an accurate description of what's going on. But I don't think we'll see any winners if we don't fix that, so we need to refocus, I think, on the overall goal of this program. Use the market to drive down costs to make Medicare more financial stable and secure; and, it's a lesson I think we would be wise to use in the entire health system.

I think we are going to hear some comments about accreditation and I think that would be a good way to move ahead in terms of making sure that those providers are doing a good job. So, I look forward to the testimony today. I thank the Chairman for this hearing and I yield back my time.

Chairman STARK. We will now hear from the acting administrator of the Centers for Medicare and Medicaid Services, Mr. Kerry Weems.

Kerry, welcome back to the Committee, and we have your prepared testimony and your colorful exhibits. Why don't you proceed to enlighten us or expand on your testimony any way you'd prefer.

STATEMENT OF KERRY WEEMS, ACTING ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. WEEMS. Thank you.

Good afternoon, Mr. Chairman. It's a pleasure to see you again, Mr. Camp.

I am very pleased to be here today to discuss the durable medical equipment prosthetics, orthotics and supplies competitive bidding program. I think this will be an excellent opportunity to dispel some of the rumors and talk about some of the facts.

This major initiative will reduce beneficiary out-of-pocket costs and improve the accuracy of Medicare's payments, help combat fraud, and ensure beneficiary access to high quality items and services. The initial round of competitive bidding is now complete, the bidding window officially closing on September 25, 2007.

We received a total of 6,209 bids; and, of the bids received, 1,335 were winning bids. We exceeded our target on small supplier participation and offered 64 percent of the contracts to small suppliers. As of April 18, 2008, 1,254 contracts have been signed out of those offered, translating to a 96 percent acceptance rate. We expect to be able to announce the contract awardees next week.

When the new payment rates take effect on July 1st for Round I bidding areas, the beneficiaries will begin saving money on ten of the most commonly used durable, medical equipment supplies such as power wheel chairs, oxygen, and diabetic testing strips.

Let me give you an example of these savings. This is a box of blood, glucose test strips with 100 in the box. In Cleveland, under the current fee schedule, the price of this exact box is $73.86, of which Medicare pays $59.09, and the beneficiary pays $14.77. Due to a successful, competitive bidding program, on July 1st, this same box in Cleveland will drop to $42.00. That's a 43 percent savings, and it's worth $6 and $37, per box, to the beneficiary, or $70 a year.

Let's take another example. Power wheelchairs, as you can see on the chart to my right, beneficiaries in Miami currently pay $805 for this particular wheelchair. Medicare pays 80 percent of the cost or $3,219. Now, after competitive bidding, the beneficiary in Miami will pay $563; and, Medicare's payment will drop to $22.53. It's a clear example of how the program is going to save both the beneficiary and the government money.

CMS is conducting an aggressive, education and outreach campaign to ensure that every beneficiary, partner, provider, and supplier knows how to use the program and to ensure a smooth transition on July 1st. As you can see from the second chart in front of you, CMS has begun a significant outreach campaign.

We started with several education activities ranging in activities with various media outlets to list serve announcements and training. Later this month, we will be announcing Round I suppliers, and we will be posting them to Medicare.gov, Our website. Will feature a supplier finder tool with contract supplier location information as well as a list of the products a particular supplier will offer. This will not only assist the beneficiaries, but also the providers.

In June we will conduct a direct mailing to all Medicare beneficiaries in the Round I area. This mailing will contain a letter, a brochure that outlines a new program and list of all contract suppliers in their area. Medicare has developed the beneficiary fact sheet; and, this will be not only available on our Web site but through partner groups and through physicians. Our partner groups are crucial to a smooth transition and we will be relying heavily on them to assist us. My staff and I have been in contact and will continue to be in contact with our partner groups to educate them on this program.

CMS will monitor the performance of contract providers through beneficiary satisfaction surveys, tracking the volume of questions

and complaints that SHIPs and 1–800–Medicare receive will track the shift from non-contract to contract suppliers for competitively bid products comparing before and after July 1st.

We will track the number of advance beneficiary notices issued by non-contract suppliers and competitive bid areas for competitively bid items to gain insight into where the beneficiaries are obtaining their products. All of these activities will help us keep current on what's taking place on the frontlines.

Once our program begins, our regional offices will respond to general inquiries from beneficiaries. They may also refer questions and complaints to 1–800–Medicare, which will be the primary point of contact for beneficiaries. Questions or complaints can also be referred to the claims processing contractor or the local Ombudsmen. All questions and complaints will be tracked for internal reporting purposes.

CMS is committed to the success of this program. We set out to provide the beneficiaries with quality items and services; and at a lower price from reliable suppliers in their communities. We have the lower price. We have reliable suppliers, and we are in the process of educating beneficiaries on this new program. Our extensive monitoring network will signal any issues that arise and allow us to move to correct them quickly and efficiently.

I appreciate your time and the invitation to testify before you today. I'd be happy to answer any questions you have at this time or address any concerns you have about the process to date.

[The prepared statement of Kerry Weems follows:]

STATEMENT OF

KERRY WEEMS

ACTING ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

DMEPOS COMPETITIVE BIDDING PROGRAM

BEFORE THE

HOUSE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

May 6, 2008

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Testimony of
Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

Before the
House Committee on Ways and Means
Subcommittee on Health
On
DMEPOS Competitive Bidding Program
May 6, 2008

Good afternoon Chairman Stark, Representative Camp and distinguished members of the Subcommittee. I am pleased to be here today on behalf of the Centers for Medicare & Medicaid Services (CMS) to discuss the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program mandated by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. This major initiative will reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare's DMEPOS payments, help combat fraud, and ensure beneficiary access to high quality DMEPOS items and services.

Overview

CMS is the largest purchaser of health care in the United States, serving over 92 million Medicare, Medicaid, and SCHIP beneficiaries. Medicare alone covers roughly 44 million individuals, with total Medicare benefit outlays projected to reach $499 billion in Fiscal Year (FY) 2009.[1] Each year, DMEPOS suppliers provide items and services including power wheelchairs, oxygen equipment, walkers and hospital beds to millions of people with Medicare. Appropriate Medicare payment amounts for DMEPOS are especially important considering the growth in expenditures for these items.

Medicare currently pays for DMEPOS items and services using fee schedule rates for covered items. In general, fee schedule rates are calculated using historical supplier charge data that may not be reflective of an appropriate payment amount for today's

[1] Department of Health and Human Services, Budget in Brief: FY 2009.

market. Relying on historical charge data has resulted in Medicare payment rates that are often higher than prices charged for identical items and services when furnished to non-Medicare customers. Medicare beneficiaries and taxpayers bear the cost of these inflated charges.

Table 1: Illustrative Comparison Prices Pre-Competitive Bidding

DMEPOS Device (rank by use)	*CMS Fee (% above average online price)*	*Illustrative Internet Pricing*	*CMS payment above average online price*
Oxygen concentrator (#1)	$2,380 (+352%)	$677	$1,703
Standard power mobility device (#3)	$4,023 (+185%)	$2,174	$1,849
Hospital bed (#4)	$1,825 (+242%)	$754	$1,071
Continuous positive airway pressure device (#5)	$1,452 (+517%)	$281	$1,171
Respiratory assist device BIPAP (Bi-level Positive Airway Pressure) (#18)	$3,335 (+247%)	$1,348	$1,987

Under the new DMEPOS competitive bidding program, beginning in 10 metropolitan statistical areas (MSAs) on July 1, 2008, Medicare payment to suppliers will be calculated based on competitive bids submitted by accredited suppliers (meeting both quality and financial standards) who were awarded contracts in designated competitive bidding areas. Winning suppliers then compete to serve beneficiaries on the basis of quality and customer service. Requiring suppliers to submit bids, including information on price, accreditation, and financial standards will ensure access to high-quality medical equipment at a more reasonable price to beneficiaries and the Medicare program. These changes, which result in more accurate pricing and improved oversight, also support CMS' efforts to reduce Medicare waste, fraud and abuse.

Beneficiary Savings

The success story of DMEPOS competitive bidding is the amount of money that beneficiaries will save as a result of lower coinsurance across the board for these

products. Competitive bidding has successfully reduced the amount Medicare will pay and has brought the payment amounts in line with that of a competitive market. When fully implemented in 2010, the program is projected to save Medicare and taxpayers $1 billion annually[2] – and these savings will directly translate to lower coinsurance for beneficiaries. Further, the projected overall savings to Part B of the Medicare program should slow the annual increase of the Part B premium Medicare beneficiaries pay each month.

Across all 10 MSAs and in each product category, beneficiaries will see an average savings of 26 percent when the new payment rates go into effect July 1, 2008. For example, beneficiaries in Orlando who use oxygen will save 32 percent. Before competitive bidding, Medicare paid $199.28 a month for oxygen rental in Orlando and after the bid process; the price has been reduced to $140.82 per month. The beneficiary, who has been paying $39.86 per month, will soon be paying $28.17 per month, a savings of $140 per year. In Charlotte and Cincinnati, beneficiaries will save 30 percent, Miami beneficiaries will save 29 percent, Pittsburgh 28 percent, Cleveland 27 percent, Kansas City 25 percent, Dallas 23 percent and Riverside 22 percent[3].

Average savings generated for these commonly used items, for which Medicare pays 80 percent and beneficiaries pay 20 percent of the allowed amount following payment of the annual Part B deductible, is summarized in the following chart[4]:

Item/Period of Service	Current Allowed Amount**	New Allowed Amount**	Medicare Savings 80% of Difference	Beneficiary Savings 20% of Difference
Concentrator				
Per month	$199.28	$140.82	$46.77	$11.69

[2] Federal Register, April 10, 2007, page 18079
[3] CMM data derived from bid results
[4] http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2993&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date

Per year	$2,391.36	$1,689.84	$561.24	$140.28
Per 3 years*	$7,174.08	$5,069.52	$1,683.72	$420.84
Hospital Bed				
Per month	$140.46	$99.28	$32.94	$8.24
Per 13 months*	$1,474.78	$1,042.46	$345.86	$86.46
Diabetic Supplies				
Per month	$82.68	$47.53	$28.12	$7.03
Per year	$992.16	$570.36	$337.44	$84.36
Per 3 years	$2,976.48	$1,711.08	$1,012.32	$253.08

* Beneficiary takes over ownership of equipment after end of rental payment period
** 20% of current and new allowed amount is paid by the beneficiary out-of-pocket

In the competitive bidding areas, Medicare suppliers are currently paid based on fee schedule amounts that average $82.68 per month for diabetic testing supplies (100 lancets and test strips) of which the beneficiary pays 20 percent (approximately $16.54 per month on average). The payment is the same regardless of whether the supplies are mailed to the beneficiary's home or purchased at local storefronts (e.g., pharmacies). Under the competitive bidding program, the average Medicare allowed monthly payment amount for these supplies in the competitive bidding areas will be reduced by 43 percent from $82.68 to $47.53, in those cases where the beneficiary chooses to obtain the supplies on a mail order basis. If the beneficiary does not wish to receive their replacement testing supplies on a mail order basis, they can elect to obtain them from a local storefront with no reduction in the allowed payment amount or beneficiary coinsurance amount.

Outreach

CMS is making great efforts to ensure the program's success. Our outreach plan includes extensive communication to four major categories of stakeholders: beneficiaries, partner groups (the local Area Agencies on Aging, the State Health Insurance Assistance Programs (SHIPs), beneficiary advocacy groups and other local organizations that come in contact with Medicare beneficiaries), providers (doctors, social workers, discharge planners and others), and DMEPOS suppliers (including the new contract suppliers, non-contract suppliers and grandfathered non-contract suppliers).

Our beneficiary outreach will include a direct mailing to all beneficiaries in the Round 1 MSAs, which will contain a letter, a brochure that outlines the new program and a list of all Medicare DMEPOS contract suppliers in their MSA. A beneficiary fact sheet is also available, and will be available through partner groups and providers. We will also rely heavily on our partner groups to assist in this transition. My staff and I have been in contact with, and will continue to meet with partner groups to educate them on this program and ask for support as the program is implemented.

Provider outreach includes doctors, social workers, referral agents, discharge planners and others. This information is delivered through the Centers for Medicare Management listservs, Medicare Learning Network Matters articles, training sessions, and teleconferences. Provider outreach aims to educate providers on how to communicate with the beneficiary about this new program and where to refer their Medicare beneficiaries who need DMEPOS. The communication pieces are delivered through the same avenues as the technical program requirements as well as through local and national medical, social work, referral agent and discharge planning organizations. We are considering conducting a direct mailing to the providers as well.

DMEPOS suppliers are reached through the provider outreach method as well as through the Competitive Bidding Implementation Contractor (CBIC). Throughout the bidding process, the CBIC, in conjunction with CMS, delivered information and messages to suppliers to assist in understanding the program and its requirements through email messages, the CBIC website, bidders' conferences, teleconferences and direct conversations. Soon, a program manual, outlining technical program requirements including policies and claims processing requirements will be available to suppliers on the CMS website. All suppliers, including the new contract suppliers, non-contract suppliers and grandfathered non-contract suppliers will receive an email notice that information about program requirements is available.

Our outreach strategy is administered both at the national and the regional level. Our CMS Regional Office staff have targeted local organizations, including local Chambers

of Commerce, State Departments of Insurance and local elected officials to request that they share information with their members or constituents.

Once the program begins, Regional Offices may respond to general inquiries from beneficiaries and stakeholders and may refer inquiries/complaints that are beneficiary or claims specific to 1-800-MEDICARE, which will be the primary point of contact for beneficiaries. Inquiries and complaints will also be referred to the DME claims processing contractor or local ombudsman depending upon their nature and scope. Inquiries and complaints will be tracked for internal reporting purposes.

In order to ensure that beneficiaries are able to access quality DMEPOS, we will be monitoring the program closely at multiple levels. CMS is committed to ensuring a smooth transition for beneficiaries, providers and suppliers when the new payment rates take effect on July 1, 2008.

- The performance of contract suppliers will be monitored through beneficiary satisfaction surveys that measure beneficiaries' level of satisfaction with the services they receive under the competitive bidding program.
- CMS will track the number of questions SHIPs receive about DMEPOS issues.
- CMS will track volume of questions and requests for DMEPOS information on 1-800-MEDICARE.
- CMS will track payments and claims to non-contracted suppliers for grandfathered supplies.
- CMS will track number of Advance Beneficiary Notices (ABNs) issued by non-contract suppliers in a competitively bid area (CBA) for competitively bid items.
- CMS will track the shift from non-contract to contract suppliers for the DMEPOS competitively bid products, comparing before and after July 1 and over time.

Bidding

The initial round of DMEPOS competitive bidding (Round 1) is now complete with the bidding window officially closing on September 25, 2007. We received a total of 6,209 bids for the competitively bid products across all 10 Metropolitan Statistical Areas

(MSAs). Of the bids received, 1,335 were winning bids. Our target for small supplier participation was exceeded, with 64 percent of contracts offered to small suppliers. Winning bids were offered a contract and as of April 18, 2008, 1,254 contracts have been signed by the suppliers, a 96 percent acceptance rate.

In order to ensure that bidders were fully informed about this new program, CMS made a significant effort to educate and communicate with potential bidders on the bidding process, including, the required documentation, and the rules and procedures for submitting a successful bid. Preliminary education began months before the final regulation was issued, and the formal education campaign began on April 2, 2007, the day the final regulation was released. Also in April 2007, CMS hosted a special Open Door Forum on DMEPOS competitive bidding in which more than 1000 suppliers participated. Prior to opening the supplier bid window on May 15, 2007, CMS established a dedicated website[5], with a comprehensive array of important information for suppliers, including a tool kit, fact sheets, webcasts, and questions and answers. CMS also held Open Door Forums, bidders' conferences, and sent listserv announcements in order to disseminate key information about the program.

CMS established a formula for selecting the number of winning bids to ensure that more than enough suppliers were selected to meet the demand for DMEPOS in a particular area. This means that beneficiaries will have access to the services they need, and that competition among winning suppliers, based on quality, customer service, will provide beneficiaries with good choices on where they seek care.

The program includes an anti-discrimination policy, requiring suppliers to provide the same items to Medicare beneficiaries as they do for their other customers. Additionally, CMS is initiating a product transparency program and will be posting a list of all suppliers and the brands they carry on our website to facilitate choice for beneficiaries and their families.

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[5] www.dmecompetitivebid.com

Finally, important aspects of this new program are the quality standards, accreditation program, and financial standards. Accreditation and quality standards will result in improved quality and customer service, while financial standards will ensure that Medicare contracts with financially sound suppliers that are able to meet beneficiaries care needs for the long term. For example, this will diminish concerns about substandard suppliers that have less than satisfactory business practices, a substantial problem in some areas of the country. These programs will result in improved oversight by CMS, and improve the quality of suppliers serving our beneficiaries.

Conclusion

The first round of the competitive bidding process has proven to be successful. Medicare beneficiaries will realize, on average, a 26 percent savings on their commonly used DMEPOS. CMS has already begun an aggressive outreach and education campaign in order to ensure a smooth transition come July 1. We set out to provide beneficiaries with quality DMEPOS, at a lower price, from reliable suppliers in their communities. We have the lower price, we have reliable suppliers and we are in the process of educating beneficiaries of this new program. Our extensive monitoring network will signal any issues that arise and allow us to move to correct them quickly and efficiently.

Chairman STARK. Well, thank you.

I think our concerns are legion; and I guess I will just pick on what I think the process, I have no quarrel with bidding, is one that causes a great deal of unnecessary concern. I would just point out to you that the Federal Government goes to a lot of extremes.

I mean, we do have no bid contracts with Bechtel and other companies like that where we just award it to our friends. Then, GSA on the other hand buys 10s, if not hundreds of thousands of vehicles. They do not give the Chevy dealer in Washington, D.C. an exclusive, if that Chevy dealer bids lower. They happen to have the manufacturer's bid, and then the manufacturer ca determine where the car is delivered, through what dealer.

In the case of automobiles, if there's some preparation required by the dealer or added equipment, the manufacturer pays the dealer. But there they're principally dealing with three or four major suppliers to bid, major manufacturers to bid, and the suppliers are all still allowed the dealers to continue.

You have a picture here of a wheelchair in Miami where, I guess, we've saved a thousand bucks, the Federal Government; but is it not correct that in Miami there will be only one dealer that will provide these wheelchairs?

Mr. WEEMS. That's not correct. No.

Chairman STARK. Well, how does that happen to be?

Mr. WEEMS. The way the bid process worked was we asked for bids.

Chairman STARK. Yeah?

Mr. WEEMS. We also estimated we knew historically the number of wheelchairs that were provided in that area.

Chairman STARK. Okay?

Mr. WEEMS. We asked suppliers for an estimate of their capacity, but we'd let no supplier go above 20 percent of the market.

Chairman STARK. So, it's got to be five dealers, minimum. How many were there before the bidding process do you suppose, 100?

Mr. WEEMS. I would not speculate, sir.

Chairman STARK. Whoa, wait a minute. You ought to know. I don't want you to speculate. How can you be doing this if you don't know?

Mr. WEEMS. I can provide it for the record, if you like.

Chairman Stark. Okay, well, let's suggest that there were 50. So, you just put 45 of them out of business. What good does that do you?

Mr. WEEMS. Well, 19 were successful in that area.

Chairman STARK. Yeah, but you told me you are only going to take five.

Mr. WEEMS. No. No. No, if they said they could take 20 percent of the market, then we would count it.

Chairman STARK. And 19 had the same bid?

Mr. WEEMS. No. That's not the way the bidding process works. Sorry. We took their estimates of capacity up to market clearing up to the point where all the capacity in the market would be taken. They had each bid a price; and, at that point, we took the median bid from that successful group. That's the way the price was determined.

Chairman STARK. Why didn't you take the low bid?

Mr. WEEMS. We took a look at it. We wanted to make sure we would have enough suppliers in the market. The median bid was the place that we chose.

Chairman STARK. But basically you just set the price, didn't you?

Mr. WEEMS. We chose the medium price of the prices bid.

Chairman STARK. That sounds like price setting to me. You may want to call it something else, but I think Boeing would like to have you arrange for taker bids, but my point is that sometimes you're bidding and sometimes you're not. When it suits your convenience and you manage to get an awful lot of suppliers all steamed up, one would think that you could find the savings and still allow many of these businesses to continue.

In your testimony you didn't suggest any changes that you might make in the program. Are there none that you can think of that would improve the program?

Mr. WEEMS. I think the change we would make for Round II is to make it very, very clear to bidders that the responsibility lies with them for supplying complete documentation for a bid.

Chairman STARK. So, it's not your fault; it's theirs. What you're really saying is you want to make it clear to the bidders that if they can't understand your instructions, they're out of the game.

Mr. WEEMS. If they're unable to provide adequate documentation, yes.

Chairman STARK. What if you're unable to provide instructions that are intelligible. Did you ever think of that?

Mr. WEEMS. Well, we did think of that and we had a number of suppliers who were able to provide us with completely documented, successful bids.

Chairman STARK. So, that absolves CMS of any, in other words, what you're saying to this Committee is there's nothing that you think is wrong with this system.

Mr. WEEMS. I can't think of anything that I would trade it for.

Chairman STARK. That's all right. Thanks. That shows your usefulness as a witness.

Mr. Camp.

Mr. CAMP. Well, I would just have to say that Mr. Weems, this is process where some people were not allowed to bid; and, so what's happened is there's an exclusive group of providers that are now going to be providing this equipment; and, I think we both agree that we've had a decade of testimony from GAO that Medicare is paying higher than market rates for DME.

But, what I would like to hear from you is a way to reform what you've been doing, because I would agree with Mr. Stark that I don't think this process has been one that stands scrutiny. So, if you could help us with a way to move forward, and this is not competitive bidding. I mean that may be the term it has, but it is a structured price setting and I think there's another way to design this to get the result where there's, you know, more competition brought into this system. Yet, there's still choice of providers.

I know that there'll be at least five providers from your testimony. No one can have more than 20 percent of the market, but I don't see any problem with having more than five providers, or more than 10 or 15 providers in an area. Particularly what I am

concerned about is information I have been hearing that some providers are going to parachute into areas of the country that they have not had any history; no infrastructure.

I do think that not all this equipment is just dropped off. There is a service aspect to durable, medical equipment. Sometimes you get it and it doesn't work and you need to get another one. So I think the goals that you are trying to achieve are laudable. I understand those and I appreciate those.

What I would like to hear from you is not that everything is okay and we are just going to move forward with this system that we have designed, but is there some way that we can improve upon this, because I think the contractor who was hired to implement this has not done you a good service.

So, if we could find a way to move forward and accomplish the goals that we have been hearing about for more than a decade before this Committee, but, so, I guess I'd like to hear from you some ideas on how to move forward with that. I think the comment on accreditation and why not have more bids and in the structured bid setting I just have some problems. So, I guess I would like to hear your comments on that.

Mr. WEEMS. Well, first of all, we had to be obedient to the statute for competitive bidding; and that statute clearly contemplated that there would be unsuccessful bidders. That the statute contemplated people would bid a price that would be competitive, where they could go and achieve a market share.

Now, like you, when I heard reports that a large number of bidders had been disqualified for reasons of documentation, I was very concerned about t hat. So, I sent a team of Federal officials down to where the documents were actually received; and, for bidders who said they were wrongly excluded, we look through 100 of the bids and we found that the contractor was correct, that items were missing. In fact, in several of them there was a cover note that told us there were items missing.

Mr. CAMP. I know my time is about to expire, but let me suggest something.

If you were to provide a 60-day window to re-examine the bids that were disqualified due to lack of information, do you believe a six-month delay would be necessary? Do you think a rebid would still be necessary if you could re-examine those folks that were disqualified?

Mr. WEEMS. Well, a rebid would be costly. We have looked at those that were disqualified, two-thirds of them would not have made it on price, anyway. So, only one-third of them were.

Mr. CAMP. Is that based on a sample? Or, is that based on looking at all of the bids that were disqualified?

Mr. WEEMS. I believe that is based on looking at all of them. So, you know, two-thirds of them were not even in the competitive range.

You know, there are improvements we could make in the on-line bidding system. That did not work particularly well in the fall of this year, actually, in the summer. So, we extended the bidding window for 60 days to be able to allow suppliers to come in. We obviously will need to work a little bit more on supplier education.

But, actually, I think the results of this round will provide substantial education.

Mr. CAMP. Well—and I realize my time has expired—I just want to say quickly is first these bidders were told if they didn't have sufficient information they'd be contacted. I realized that changed twelve days before the bids closed; but, if you could re-examine those bids in a 60-day window that didn't have adequate information and give them a chance to submit that. That's my proposal, if you'd think about that.

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

Chairman STARK. Thank you.

Mr. Thompson, would you like to inquire?

Mr. THOMPSON. Thank you, Mr. Chairman. I do.

Mr. Weems, I just want to pick up on something that the gentleman from Michigan mentioned. Your answer, you said something along the lines of this round will tell us a lot about are we going to the next round.

Is there any discussion or consideration being given to delaying the second round 'til we find out what we learned from Round I?

Mr. WEEMS. We haven't announced a full schedule yet for the second round. The statute requires that.

Mr. THOMPSON. Are you considering delaying it to learn from?

Mr. WEEMS. We are considering the schedule that we would lay out given what we have learned here.

Mr. THOMPSON. That will give us time to take away some lessons learned from Round I?

Mr. WEEMS. Of course. The statute requires that we do the competition in 2009.

Mr. THOMPSON. I'd like to ask you about this proposal and how it affects an area that is near and dear to me. That's rural American.

Mr. WEEMS. Yes?

Mr. THOMPSON. About 30 percent of the suppliers are in rural areas and it takes you longer to get from one spot to another. There's greater distance to travel, gasoline at $4 plus a gallon. The costs all start to tack up. What are your plans for dealing with the disparity that the folks in rural areas are going to find themselves slapped with?

Mr. WEEMS. Well, in the first and second rounds that we have announced so far, those were required to be in MSA. So, they are not in rural areas. We have a decision in front of us that is still quite distant and will likely be made in future administration about exactly what we do in rural areas. So, right now, we are not contemplating competitive bidding in rural areas at this point. Though I think that the beneficiaries in rural areas who look at the price savings that those in urban areas have might want those prices.

Mr. THOMPSON. Might have what?

Mr. WEEMS. Might want those prices.

Mr. THOMPSON. Well, they may want the prices, but it's a distinctly different area and there's different costs that are associated with it. There's access questions that have to be asked. If you have to drive three hours in order to get your equipment or to have it serviced, repaired or have warranty worked on it, these are all

problems that folks in rural areas experience that folks in the city who oftentimes make these policies have no idea what life in the rural area is like. I'd like some assurances that rural issues, concerns and access for these folks are in fact taken into consideration.

Mr. WEEMS. But they are, and we have exempted them.

Mr. THOMPSON. I guess I'd like more than just your nod and word that they are. I'd like to better understand how this is being dealt with.

Did you guys take into consideration a supplier's experience or lack of experience with a given type of equipment before you made these awards?

Mr. WEEMS. We took into account a supplier's ability to supply the market. We took into account whether or not they were an accredited entity.

Mr. THOMPSON. But how about their actual experience with providing a certain type of equipment; providing a service for that certain type of equipment? How do you determine if one is qualified to do that at the same level that beneficiaries were experiencing before?

Mr. WEEMS. Well, unlike the current program, we actually require our bidders to be accredited.

Mr. THOMPSON. Accredited by whom?

Mr. WEEMS. We picked various accrediting bodies for whom they could go to accreditation. Currently, suppliers are not required to be accredited. We do expect that all of them will be accredited by September of 2009, but under the current regimen, they are not accredited.

Mr. THOMPSON. I'd like to know what that accreditation takes in in regard to the standards that they have to meet. I want to know what it is. I think there's some basic problems that I think we all need to understand.

Mr. WEEMS. General provider accreditation requires we have standards for set up and delivery, training and instruction.

Mr. THOMPSON. Whose standards? What are the standards? Who sets them? Who reviews it? Is there a process by which folks can wage complaints and get redress on those complaints?

Mr. WEEMS. Of course, and I can provide you in writing the various standards that we have. But we have more beneficiary protections now under competitive bidding than there are in the previous program, and we added additional protections for quality standards for oxygen and for complex rehab chairs.

Mr. THOMPSON. Mr. Chairman, I would hope that through the Committee you would re1quire that they submit this so we have an understanding of how in fact they are accrediting these people to make sure that they are qualified and able to provide the services that all of our constituents are going to be dependent on. Thank you.

Chairman STARK. I appreciate the gentleman.

My concern, for example, how the scooter store, some hundreds of miles away, gets to be an oxygen provider. That stretches the imagination of accreditation. But maybe it's because they have those horns on the scooters, and that squeeze the bulb and you get oxygen.

Would the gentleman from Texas, Mr. Johnson, like to inquire?

Mr. JOHNSON. Thank you, Mr. Chairman. I appreciate you having this hearing.

I know you're not a doctor, but do you have any medical experience at all?

Mr. WEEMS. No.

Mr. JOHNSON. How can you run an organization like this without medical experience?

Mr. WEEMS. A number of my predecessors have not been clinicians.

Mr. JOHNSON. I know. I've griped about that too.

Have you ever done any work other than for the government?

Mr. WEEMS. My entire professional career has been as a civil servant.

Mr. JOHNSON. How many years is that?

Mr. WEEMS. I mark 27 years with the government this month; 25 with HHS this month.

Mr. JOHNSON. Okay, thank you. You know, you set the price for the medical equipment. We've already determined that. On hearing from suppliers in the third district—it's Dallas essentially—and how the implementation is affecting them, I become concerned.

You know, Congress can have all the good intentions in the world, but the agency in charge is putting Congress' ideas into practice missing some mark, it puts us in a difficult position. The number one issue I've heard about is the same all these other questioners have heard about. How many suppliers submitted bids to CMS for Round I out of the Dallas area?

Mr. WEEMS. Let me see.

Mr. JOHNSON. I'll help you, about a thousand.

Of those totals, how many of those suppliers were initially rejected for some reason other than the actual amount of the bid?

Mr. WEEMS. About 508.

Mr. JOHNSON. 600 is the number I've got, but that's close.

Of those suppliers, how many filed a 30-day review of their bid package with a contractor to look at insufficient financial disclosure?

Mr. WEEMS. I don't have the Dallas area, but 346 filed total.

Mr. JOHNSON. About 300. Now, it seems to me that these numbers suggest more of a systemic problem rather than a supplier here or there forgetting to include a piece of paper with their bid package.

Would you not agree with that?

Mr. WEEMS. I would say that there is a problem with the fact that certain financial documentation was not supplied.

Mr. JOHNSON. Yeah, but you had no cross-talk between the guys submitting bids to tell them that they didn't have all the information there; and, according to what I'm hearing from you, the contractor was not telling you whether they got all the paperwork or not. Is that true or false?

Mr. WEEMS. I was informed of that after the bid window closed.

Mr. JOHNSON. Okay. You know, would the premise of competitive bidding program being you will only get a contract if you bid low enough, and then you set a higher number, there's some con-

cerns that massive consolidation may negatively impact the competition in bid years to come.

How do you see this process unfolding in the next year or within the next 3 years let's say?

Mr. WEEMS. I see substantially more competition, especially as we move to Round II, the other 70 MSAs. I think that we'll have more companies come in to the market to try and capture market share. We will have lower prices and drive down the cost for the government and for beneficiaries.

Mr. JOHNSON. Well, as my friend here pointed out, I think a reduction in suppliers ultimately could lead to less competition and higher prices.

You don't agree with that statement?

Mr. WEEMS. I'm not sure that I accept the premise. There'll be a reduction in suppliers.

Mr. JOHNSON. Well, if you keep setting limits on them and putting people out of business, I don't know how you could help but understand that.

Did you do anything to ensure that contracted suppliers have a sufficient capacity to supply the products?

Mr. WEEMS. We looked at their bids, looked at their business plan; their capacity to supply and as I said we only let any individual supplier say that they could supply up to 20 percent of the market even if they made claims being able to supply more than that. If indeed the company was expanding beyond their current capacity and had a business plan to do that, we required stronger financial assurances from the company before we would allow that bid to come in at that capacity.

Mr. JOHNSON. Well, how did you determine whether the financial capability was strong or not?

Mr. WEEMS. Well, the financial documentation required in the bid allowed us to do that because we were able to compute certain financial rations that would tell us the financial strength of that company.

Mr. JOHNSON. Okay. Thank you, Mr. Chairman. I appreciate the time.

Chairman STARK. Mr. Becerra, would you like to inquire?

Mr. BECERRA. Thank you, Mr. Chairman.

Mr. Weems, thank you very much for being here.

Mr. WEEMS. It's good to see you, sir.

Mr. BECERRA. Let's see if I can continue along the lines of my friend Mr. Johnson's questioning. First, let me ask this.

Is a contractor who wins a contract from CMS able to subcontract some of those services based on that awarded contract?

Mr. WEEMS. Absolutely, and that's indeed what I expect to happen when we announce the winning suppliers next week, that many will want to subcontract.

Mr. BECERRA. So, are the qualifications of a subcontractor taken into account by CMS in the process of awarding a bid to a prime contract?

Mr. WEEMS. Not in the process of award, because those contracts don't exist yet. So, the liability and responsibility remains with the prime contractor to make sure that the services are rendered as provided for in the contract.

Mr. WEEMS. That's correct. We will hold that contractor responsible for the services they contracted for.

Mr. BECERRA. So, is a prime contractor able to subcontract with someone who may not have any experience in their particular field?

Mr. WEEMS. They could, yes. I'm not sure it would be in their business interest to do so, but yes, they could.

Mr. BECERRA. Is there any requirement that a subcontractor be accredited to provide the types of equipment or services that are required under the contract?

Mr. WEEMS. The contractor themselves are required. The winning supplier is required to be accredited. The same quality standards from which that accreditation arose would also be required of the subcontractor. They would not be required to be accredited at this point, but all suppliers are going to be required to be accredited as of September of 2009.

Mr. BECERRA. As I understand it though, your relationship legally is with the contractor. What the contractor does to satisfy the terms of the contract, you don't have that much oversight over them in that regard, do you?

Mr. WEEMS. In these ten areas, they are going to be under the microscope. We are going to have a high degree of scrutiny over contractor's performance, and their ability to deliver quality products to beneficiaries.

Mr. BECERRA. But you are going to have to rely on the prime contractor doing this the right way, because your legal relationship, CMS's legal relationship, isn't with the subcontractor.

Mr. WEEMS. That's correct.

Mr. BECERRA. You've already said just a minute ago that you don't interfere with the process of the subcontracting, so the subcontractor could be someone or some entity totally unfamiliar with the field that the contract with the prime contractor is for.

Mr. WEEMS. Again, perhaps not in the best interest of the contractor, but what you say is possible. Yes, sir.

Mr. BECERRA. So, why not run the thread of legal responsibility that CMS, when it gives out money and gets a contract, runs not juts to the contractor, but to any subcontractor.

Mr. WEEMS. The contract right now, and, as you pointed out, the legal responsibility, is with the contractor. They're the ones who have had the bid. They're the ones with the skin in the game and if they don't perform, we're going to take action against them. That includes the non-performance of a subcontractor.

Mr. BECERRA. The difficulty, Mr. Weems, with that is that you're not trying to remedy a situation. You're not trying to rectify a problem that may have occurred as a result of the contract because of whatever activity by the contractor in this case, in our example, with a subcontractor.

So, trying to remedy something doesn't necessarily assure us that we are going to get our money back if we over-pay or if we are defrauded. I think there is a real concern, at least some of us, I think, that this so-called competitive bidding process may not necessarily giving us everything we think we're going to get in return.

Let me before my time expires ask something else with regard to this competitive bidding process.

Doesn't it seem to run somewhat counter to intuition that we have competitive bidding in the marketplace if you limit the number of suppliers who compete?

Mr. WEEMS. Actually, it's quite intuitive to me, because when we bid a contract in government, typically, there's just one winner. Everybody who didn't win is excluded.

Mr. BECERRA. Well, now you're talking Pentagon. Let's forget about the Pentagon for now.

Mr. WEEMS. No, I mean even in HHS. When we acquire things or, you know, when we have a contract, we competitively bid it. If you don't win, you don't win and you don't participate.

Mr. BECERRA. But rather than say that we only want as many competitors as we think we'll need to satisfy the need, why not say, everyone come forward. Anyone who can match the price is eligible to compete and participate. So, this way, you always have a lot of contractors out there who are able to participate, and you ultimately, hopefully, then get the most competitive price, because you have a very open, competitive process.

But when you simply say we're going to need someone to satisfy this need of medical widgets, we need a thousand of these medical widgets, and we see that we have three suppliers there that can provide the thousand medical widgets, so therefore, we only need three suppliers. That doesn't necessarily guarantee that those three suppliers are going to give you the best price, the most competitive price. But, if you say we need a thousand widgets; everyone compete, and everyone at every point can compete, then there will be true competition to try to keep the price of those widgets as low as possible so they can get the business from the government.

Mr. WEEMS. I understand your point. First of all, the law doesn't allow for any willing provider, but second of all, if we bid and said everybody come in, it's likely we wouldn't get 26 percent discounts. Instead, we get the fee schedule again. You know, if you don't have any skin in the game, you're going to bid the fee schedule price.

Mr. BECERRA. I know my time is expired, so Mr. Chairman, I'll stop.

But, Mr. Weems, at some point I'd like to transition this conversation not in terms of DME but in terms of MA, Medicare Advantage, and see if you'll say the same things with regard to the process of competition that you provide for under the setting for Medicare Advantage participation and are compared to what you do for DME.

But I thank you for your time.

Mr. WEEMS. Yes, sir.

Chairman STARK. Mr. English, would you like to inquire?

Mr. ENGLISH. Yes, thank you, Mr. Chairman.

Mr. Weems, when a large hospital-based DME company fails to secure Medicare contract, many patients and hospitals are affected.

What are plans at CMS for transition in states where the hospital-based DME companies currently serving many hospitals and Medicare patients have not been offered Medicare contracts.

Specifically, my interest after July 1st, 2008, several large health organizations will no longer be able to accept Medicare patients including in my region, UPMC, which serves 13 hospitals, and Van-

tage, which serves 12 hospitals. What are the transition plans for these patients in the hospitals?

Mr. WEEMS. Thank you for the question. Congressman, I am not going to be able to speak about the particulars.

Mr. ENGLISH. I'm happy to entertain it.

Mr. WEEMS. All right. I will give you a general answer.

The particulars of this are still covered by the procurement laws.

Mr. ENGLISH. Yes.

Mr. WEEMS. I expect that in hospital-based settings that they will subcontract with a winning supplier. That's going to be an area where we're going to have very good contact with beneficiaries, so that they're going to become contract suppliers. They're just not going to, you know, in their service, and close down in a hospital.

Mr. ENGLISH. Okay. A very different kind of transition occurs for many Medicare patients who will be leaving hospitals.

What are the Medicare strategies for acquiring the new DME contractors to be responsive and timely in fulfilling their obligation to deliver equipment and services at the time of discharge from the hospital, particularly after normal business hours?

Mr. WEEMS. The people are going to be in this business to succeed. They're going to be in this business to win market share; and, with the market prices, there's going to be even more motive to capture market share. The way to do that is going to be through quality.

That is, they're going to offer higher quality services. They are also going to be accredited. They will have met quality standards that's not true today.

Mr. ENGLISH. Mr. Weems, one of the issues that has become apparent in conversations I've had with interested constituents is that there have been bids awarded to companies that have never previously provided the bidded service. I'm curious.

What is CMS's approach to this particular issue and has there been any thought to protecting the Medicare benefit by making certain that awards are given to bidders who are clearly able to provide that service and maybe with a focus on providers that are already doing this?

If in fact the other is happening, how does that equate to enhanced quality care for our Medicare patients?

Mr. WEEMS. Well, first of all, it's good to step back and look at the circumstances today. Today, anybody can move into a particular line of durable, medical equipment without that expertise. For the competitive bidding program, they had to show that they were a viable ongoing business. That's not a requirement today. They had to meet our quality and accreditation standards. That's not a requirement today; and they also had to demonstrate a business plan that would show capacity to meet the market. That's not a requirement today. Those are the kinds of beneficiary protections that are built into it.

Mr. ENGLISH. So, your argument is there's really no protection today from folks entering stepping up providing the service.

Mr. WEEMS. Absolutely.

Mr. ENGLISH. Okay. I wonder, Mr. Weems, can you offer the rationale behind the requirement for national diabetes suppliers to

bid based on a full formulary while small suppliers could bid and win by bidding on a limited number of products. I wonder, what impact will this have on patient choice.

Did CMS find that this created a disproportionate number of particularly low bids, which were based on fewer products?

Mr. WEEMS. I am going to have to provide you that answer in writing, Congressman.

Mr. ENGLISH. Very good. Thank you, Mr. Chairman.

Chairman STARK. Mr. Doggett, would you like to inquire?

Mr. DOGGETT. Thank you for your testimony, Mr. Weems.

While I certainly share a number of the concerns my colleagues have voiced, I think it is important to understand how we got to this point and there was a conclusion reached, not only by you and your office, but by a number of other groups that looked at this issue that we have been paying and are today paying significantly more for durable medical equipment that is necessary to provide quality, durable medical equipment to Medicare beneficiaries. Isn't that correct?

Mr. WEEMS. It is, sir.

Mr. DOGGETT. That's why you conceived this competitive bidding program?

Mr. WEEMS. It's why it was conceived. We are following the law.

Mr. DOGGETT. I do want to get your reaction to the question my colleague, Mr. Becerra raised, because if competition is a good way to address this problem, why wouldn't it also be a good way to deal with Medicare Advantage where we are still paying $1100 more for beneficiary than for traditional Medicare.

Mr. WEEMS. In Medicare Advantage the payment rates are based on a county benchmark system within that benchmark system, plans do compete.

Mr. DOGGETT. Well, they don't compete enough to not result in a situation that's been estimated at a cost over 10 years of $150 Billion more than if we just covered them with traditional Medicare. So, there may be some competition, but it has yet to lower prices; and, as you know, your actuary has been unable to give us any future date by which we won't be paying out billions of dollars more to these plants.

Why can't they compete in the same way that you propose to occur here?

Mr. WEEMS. The payment for Medicare Advantage plans are based on a county benchmark that's in statute. The payment rate is fixed by statute on a county benchmark level.

Mr. DOGGETT. Well, I'll accept your answer, but respectfully disagree with you that the system is not working and it is causing us a much greater cost to sustain any quality of care than any of what we are talking about today.

But, focusing on today, you will recall that back in 2001 the HHS Inspector General testified to congress that durable medical equipment providers, that we were paying them for products that were sometimes never delivered and we were paying for more expensive items than what was actually received. That was one of the initial voices of concern; and then in 2004, the GAO indicated that Medicare lacks the capability to identify specific items provided to bene-

ficiaries, because suppliers' claims use broad codes and don't identify the specific item.

I gather that that's still a problem, and my question to you apart from competitive bidding, since I've heard that there are concerns that their incentives to substitute lower price or lower quality items for higher priced items is has CMS or HHS ever considered establishing some kind of serial number or identification program so that you can track individual pieces of durable, medical equipment, and follow them through the claims process?

Mr. WEEMS. I know of no attempt.

Mr. DOGGETT. No study of that? I mean, why wouldn't that be feasible?

Mr. WEEMS. Well, for many of these pieces of equipment, you know, some can be, you know, quite small.

Mr. DOGGETT. Some of the reference to scooters or motorized wheelchairs are pretty substantial. Why couldn't you use a serial number system on some of these items?

Mr. WEEMS. That might be something that we can look at. I mean, one of the frustrations, sir, as you well know, with durable medical equipment is it's supplied in the home. It's supplied outside of the public view and it is one of those. It's not quite a government acquisition, but, you now, you don't get a corresponding control number or a corresponding receipt. The government doesn't for actually having acquired the equipment.

Mr. DOGGETT. You're going to respond to a question Mr. Thompson raised about accreditation. But, as you did accreditation for these suppliers, were you looking only at financial capability or did they have to demonstrate some expertise in being able to deliver a service.

If someone was in oxygen and they were now going to provide diabetes supplies; or, if they were in motorized wheelchairs like the scooter store and they would provide oxygen, what did you look at to assure that they have the capability to provide quality products?

Mr. WEEMS. We looked, first of all, at overall ability to do delivery and set-up. Can they do that? For many of the kinds of products we're talking about, that's not very complex. But we took an additional step for two items, which are more complex, and that is for oxygen and for complex power, motor device, complex wheelchairs. We actually established higher standards for the delivery and set-up, and the capability of doing that for those two items, because they are more complex—standards which don't exist to this day.

Mr. DOGGETT. So, if the scooter store will be providing oxygen supplies, they had to meet those standards?

Mr. WEEMS. They do, yes.

Mr. DOGGETT. Just one other area. We all remember the problem some would say fiasco associated with the initial implementation of the Part D program and the claim that all you had to do was just call 1–800–Medicare.

We are now about, I guess, less than 2 months out from this program going into effect. What have you done to ensure we don't have a repeat of that? What additional training has there been and is there any, I guess, ombudsman-type office so that if folks that are counting on this durable, medical equipment have as many

problems as folks had originally with part D, that there'll be an alternative available for it.

Mr. WEEMS. That chart and the one that you have in front of you shows the various outreach activities that we have. But, let me stress two things, sir. Because you ask a very, very good question. The most important moment in all of this is when a Medicare beneficiary sits with their provider and their written prescription. They need to know what to do with it at that point. That's what we're concentrating on and we are going to give physicians a list of qualified beneficiaries.

Remember, most of this is not storefront-type material. What happens is the beneficiary takes that and then calls a number and it's delivered to their home. That's the moment that we are concentrating on. Every Medicare beneficiary in these MSAs will get a letter from us. Every provider, every supplier will get a letter from us laying out in detail. So, what happens then?

One of the things that I think is vitally important when you institute a new program is situational awareness. How do you know what's happening?

We have put together a surveillance network so that we will know what happens; and, yes, that includes calls to 1–800–Medicare. It includes calls to our SHIPs. It includes the regional offices involvement in each one of those areas. We're going to check in with the suppliers. We are going to work to get this right. I hope you are feeling better. I'm sorry, you were in an accident.

Chairman STARK. Mr. Tiberi, would you like to inquire?

Mr. TIBERI. Thank you, Mr. Chairman. Thank you for letting me sit in.

Sorry that I didn't hear your testimony. I look forward to reviewing it, Mr. Weems.

Just a couple comments, I guess, to get your comments, I guess, to get your thoughts on from things that I have been hearing and thanks for your long-term service to the Federal Government, our taxpayers.

Some would say that the entire process in which the implementation of this program has not met transparency levels that we would all be proud of in the Federal Government and that there has been a lack of information provided to both beneficiaries and suppliers and policymakers throughout the implementation of this process.

What would you say to that criticism?

Mr. WEEMS. I would strongly disagree. I think that we have done a very good job of educating our suppliers. We have an advisory Committee with them that has met six times over the course of this. We have taken considerable input from them. We have been very transparent. About the requirements, the only thing that I would say that we have not disclosed as a matter of the bid process is exactly how we use the financial rations in judging the financial viability of each bidder. We have told them what financial documentation we need. We have told them the ratios that we would use, but we have not told them how that would be scored.

That, I would say, is the one piece sort of "our audit plan," we have not disclosed.

Mr. TIBERI. So, if Members of this Committee can give you information that contradicts that, you'd be willing to look at that?

Mr. WEEMS. Absolutely.

Mr. TIBERI. Just to follow-up on Mr. English's point or one of his points the criticism that there are suppliers that could be awarded regions that they have no business model presently in may not be a concern, but after this process is put in place and you have people providing a service in a region where they have never provided a service before, if there are problems in providing a service to beneficiaries, what would be CMS's reaction to that?

Mr. WEEMS. You know, it depends on the problem. If we find somebody who is simply incapable in that region then we're going to take steps to end their contract and award it to another. So, it depends on what problems.

But, again, these suppliers bid to have a viable business model, to move into, if they're moving in, a community to actually sell product. They didn't win not to sell product.

Mr. TIBERI. But there's no advantage given to someone who has a business model within that community?

Mr. WEEMS. They might have a particular competitive advantage by knowing the community, knowing the physicians, knowing the beneficiaries. But there's no structural advantage.

Mr. TIBERI. Not with you. Not with you all.

Mr. WEEMS. Correct.

Mr. TIBERI. Thank you. Thank you, Mr. Chairman.

Chairman STARK. I just had a couple of questions. The definition of a supplier, I gather, is that person with whom the beneficiary patient has contact. Is that correct?

Mr. WEEMS. Yes.

Chairman STARK. For the most part, suppliers are not manufacturers? Certainly not necessarily manufacturers?

Mr. WEEMS. They are not necessarily manufacturers. There are some cases.

Chairman STARK. The supplier does not have to supply new equipment. Is that correct?

Mr. WEEMS. They may supply refurbished equipment, but that's true now. Yes.

Chairman STARK. They can purchase their equipment made in China, Taiwan, France. There's no real prohibition on where they buy the equipment. Is there?

Mr. WEEMS. It has to be an FDA approved, but after that, it has to meet manufacturing standards. But yes, they can acquire it.

Chairman STARK. Does the FDA approve crutches and bandages and canes?

Mr. WEEMS. Well, those aren't ones that we competitively did.

Chairman STARK. None of the supply? What about hospital beds?

Mr. WEEMS. They do, I'm told. Yes.

Chairman STARK. The FDA approves hospital beds? Imagine that.

How does one judge the quality of refurbished or used equipment?

Mr. WEEMS. The equipment has to be in good working order. It has to meet the standard of working for the beneficiary, and, you know, being of good quality.

That's true today.

Chairman STARK. I would entertain any of my colleagues if they'd like to further inquire. If not, we'll excuse you, Mr. Weems. Thank you for your considerable help in this issue and we will have our second panel.

Mr. WEEMS. Thank you, Mr. Stark; pleasure to see you again, sir.

Chairman STARK. All right. Hurry back.

We are pleased to welcome Ms. Kathleen King, the Director of Healthcare Studies at the U.S. Government Accountability Office, affectionately known as GAO; Mr. Tom Ryan from the American Association for Homecare; Mr. Peter Thomas, the Health Task Force Co-chair at the Consortium for Citizens with Disabilities; and Mr. Thomas Hoerger, a senior fellow at the Research Triangle Institute International.

We have your prepared testimony and without objection for each of you it will appear in the record in its entirety. If you would like to expand on it, change your mind or inform us in any way, please continue. We'll ring a bell here in about 5 minutes and we can elicit more details from you in the question period that follows.

Ms. King, would you like to lead off?

STATEMENT OF KATHLEEN M. KING, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. KING. Mr. Chairman, Members of the Subcommittee, thank you for inviting us here today to testify about GAO's work on Medicare payment for Medical Equipment and Supplies.

A number of you have made references to our earlier work and we have in fact done a series of reports over the last 10 years or so where we talked about cases where Medicare was overpaying of medical equipment and supplies.

In one case in 2000, we reported that Medicare paid more than the median surveyed retail price for five categories of equipments, including eyeglass frames, catheters and two types of catheter insertion trays. I just point to that as one example of our work. So, my remarks today will be based on our previously issued work.

We have said that competition is a fundamentally different way to pay for services and fee schedules based on historical charges and that competitive bidding; and, this has also come up today, difference from Medicare's usual practice of accepting any willing, qualified provider by selecting among providers based on established criteria such as price and quality.

We believe that competition could reduce Medicare spending by creating an incentive for providers to accept lower payments in exchange for their ability to retain Medicare business and to increase market share. In the demonstration of competitive bidding that happened from 1999 to 2002, approximately 50 to 55 percent of the bids from suppliers were accepted and the evidence suggests that competition helped lower payments resulted in estimated savings of 7.5 million from the Medicare Program and 1.9 million for beneficiaries who paid lower copayments.

Based on the results of the demonstration, Congress enacted the permanent program for Medicare competitive bidding that's under discussion today; and, I think, I won't elaborate on all of the elements of that except a couple; and, one is that the accreditation

process, which is new, and the fact that suppliers must submit financial documents that include income statements, credit reports and balance sheets.

In our view, this additional scrutiny could help CMS screen out providers that are not stable or legitimate businesses, and it could help reduce the improper payment rate of 10.7 percent for medical supplies and equipment which is more than double that for other Medicare providers. But we have also said that the competitive bidding program raises concerns about accessing quality of care, because it could encourage providers to cut costs by providing lower quality of care or curtailing services.

Therefore, we believe it's important and in fact adequate oversight of the program is critical. When we evaluated the competitive bidding demonstration, we made a number of recommendations to CMS, and that was that they monitor beneficiary satisfaction. That they set standards for providers to participate. That they provide beneficiaries with the choice of suppliers and that they select winning bids on the basis of quality in addition to price. One of the ways they could do that would be routine monitoring of beneficiary complaints, concerns, and satisfaction.

I should point out to you and I know you have someone on the panel today form the independent evaluation. But the evaluation of the demonstration did not see any major adverse effects on access or quality of care. There were a few concerns raised. A decline in the use of portable oxygen among new users and a possible shift away from providers making home delivery.

When you enacted the competitive bidding program, you also directed us to look at the impacts on suppliers, manufacturers and beneficiaries. We were directed to look at Access and the quality of items and services. We now have a team working on that and we have also been asked by the Committees of jurisdiction to assess Medicare's implementation of the competitive bidding program.

Mr. Chairman, that concludes my prepared remarks [continuing]. I'd be happy to answer questions.

[The prepared statement of Kathleen M. King follows:]

United States Government Accountability Office

GAO

Testimony

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

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MEDICARE

Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical

Statement of Kathleen M. King
Director, Health Care

GAO-08-767T

GAO

Highlights

Highlights of GAO-08-767T, a testimony before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

May 6, 2008

MEDICARE

Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical

Why GAO Did This Study

For more than a decade, GAO has reported that Medicare has paid higher than market rates for medical equipment and supplies provided to beneficiaries under Medicare Part B. Since 1989, Medicare has used fee schedules primarily based on historical charges to set payment amounts. But this approach lacks flexibility to keep pace with market changes and increases costs to the federal government and Medicare's 44 million elderly and disabled beneficiaries. The Balanced Budget Act of 1997 required the Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare—to test competitive bidding as a new way to set payments. CMS did this through a demonstration in two locations in which suppliers could compete on the basis of price and other factors for the right to provide their products. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to conduct competitive bidding on a large scale and suppliers to obtain accreditation.

GAO was asked to describe the effects that competitive bidding could have on Medicare program payments and suppliers and the need for adequate oversight to ensure quality and access for beneficiaries in a competitive bidding environment. This testimony is based primarily on GAO work conducted from May 1994 to January 2007, which GAO updated by interviewing CMS officials and reviewing agency documents.

To view the full product, including the scope and methodology, click on GAO-08-767T. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

Competitive bidding could reduce Medicare program payments by providing an incentive for suppliers to accept lower payments for items and services to retain their ability to serve beneficiaries and potentially increase their market share. Fundamentally different from fee schedules based on historical charges to Medicare, competitive bidding allows the market to help CMS determine payment amounts. In the demonstration, the new fee schedule amounts were based on the winning suppliers' bids for items included and 50 percent to 55 percent of the bids from suppliers were selected. Evidence from CMS's competitive bidding demonstration suggests that competition saved Medicare $7.5 million and saved beneficiaries $1.9 million—without significantly affecting beneficiary access. For the competitive bidding program, CMS required suppliers to obtain accreditation based on quality standards and provide financial documents to participate. This added scrutiny gives CMS the chance to screen out suppliers that may not be stable, legitimate businesses, which could contribute to lower rates of improper payment. CMS also evaluated the bids based on demand, capacity, and price and chose suppliers whose bids were at or under a certain amount. CMS estimates that the first round of its competitive bidding program will result in payment amounts that average 26 percent less than the current fee schedule amounts. Competitive bidding also changes Medicare's relationship with suppliers and departs from Medicare's practice of doing business with any qualified provider, because it is designed to limit the number of suppliers to those whose bids are at or under a certain amount.

Because of concerns that competitive bidding may prompt suppliers to cut their costs by providing lower-quality items and curtailing services, ensuring quality and access through adequate oversight is critical for the success of the competitive bidding program. In September 2004, GAO indicated that quality assurance steps could include monitoring beneficiary satisfaction, setting standards for suppliers, giving beneficiaries a choice of suppliers, and selecting winning bidders based on quality and the dollar amount of the bids. As competitive bidding expands, problems that beneficiaries might experience could be magnified. Therefore, continued monitoring of beneficiary satisfaction will be critical to identify problems with suppliers or with items provided to beneficiaries. As required in the MMA, GAO will review and report on the competitive bidding program's impact on suppliers and manufacturers and its effect on quality and access for beneficiaries.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss the Medicare competitive bidding program for durable medical equipment (DME), prosthetics, orthotics, and supplies—products referred to in this statement as medical equipment and supplies.[1] For more than a decade, we and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) have periodically reported that Medicare, administered by the Centers for Medicare & Medicaid Services (CMS), has paid higher than market rates for various medical equipment and supply items.[2] These overpayments increase costs to the program and to Medicare's 44 million elderly and disabled beneficiaries. CMS reported in 2007 that total Medicare expenditures for medical equipment and supplies were about $10 billion.[3]

Since 1989, Medicare has paid for medical equipment and supplies through fee schedules that list a maximum and minimum payment amount. The schedules are based on average supplier charges on Medicare claims in 1986 and 1987 and have been updated in some years to reflect inflation.[4] However, this payment approach lacks flexibility to keep pace with market changes, and as a result, Medicare often pays higher prices than other public payers for medical equipment and supplies. The Balanced Budget Act of 1997 (BBA)[5] required CMS to test competitive bidding as a new way for Medicare to set fees for Part B items and services specified by CMS, which the agency did through a demonstration focused on medical

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[1]Medicare guidance defines DME as equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. DME includes items such as wheelchairs, hospital beds, and walkers. Medicare defines prosthetic devices (other than dental) as devices that are needed to replace body parts or functions. Prosthetic devices include artificial limbs and eyes, enteral nutrients, ostomy bags, and cardiac pacemakers. Medicare defines orthotic devices to include leg, arm, back, and neck braces that provide rigid or semirigid support to weak or deformed body parts or restrict or eliminate motion in a diseased or injured part of the body. Medicare-reimbursed supplies are items that are used in conjunction with DME and are consumed during the use of the equipment, such as drugs used for inhalation therapy, or need to be replaced frequently (usually daily), such as surgical dressings.

[2]A list of related GAO products is included at the end of this statement.

[3]These expenditures reflect claims submitted April 1, 2006, through March 31, 2007.

[4]CMS has established a process to price new items that are added to the fee schedule.

[5]Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392 (1997).

equipment and supplies.[6] Competitive bidding is a process in which suppliers of medical equipment and supplies compete for the right to provide their products on the basis of established criteria, such as quality and price. About a year after the demonstration concluded, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to conduct a competitive bidding program for DME, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies on a large scale.[7]

In my testimony today, I will discuss (1) the effects that competitive bidding could have on Medicare program payments and suppliers and (2) the need for adequate oversight to ensure quality and access for beneficiaries in a competitive bidding environment. My testimony is based primarily on our previously issued work, conducted from May 1994 to January 2007, which we updated with information on the competitive bidding process by interviewing CMS officials and reviewing agency documents. We shared a statement of facts regarding this testimony with CMS and incorporated the agency's comments as appropriate. We conducted this performance audit from April 2008 through May 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, competitive bidding could reduce Medicare program payments by providing an incentive for suppliers to accept lower payments for items and services to retain their ability to serve beneficiaries and potentially increase their market share. Fundamentally different from fee schedules based on historical charges to Medicare, competitive bidding allows the market to help CMS determine payment amounts. In the demonstration, the new fee schedule amounts were based

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[6]Medicare Part B helps pay for certain physician, outpatient hospital, laboratory, and other services, and medical equipment and supplies. Beneficiaries are required to pay a monthly premium for their Part B coverage.

[7]The competitive bidding program changes the way that Medicare determines the payment amounts for medical equipment and supplies by replacing the current fee schedule payment amounts for selected items in certain areas with payment amounts based on competitive bids submitted by Medicare suppliers. Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2224.

on the winning suppliers' bids for items included and 50 percent to 55 percent of the bids from suppliers were selected. Evidence from CMS's competitive bidding demonstration suggests that competition saved Medicare $7.5 million and saved beneficiaries $1.9 million—without significantly affecting beneficiary access. For the competitive bidding program, CMS required suppliers to obtain accreditation based on quality standards[a] and provide financial documents to participate. This added scrutiny gives CMS the chance to screen out suppliers that may not be stable, legitimate businesses, which could contribute to lower rates of improper payment. CMS also evaluated the bids based on demand, capacity, and price and chose suppliers whose bids were at or under a certain amount. CMS estimates that the first round of its competitive bidding program will result in payment amounts that average 26 percent less than the current fee schedule amounts. Competitive bidding also changes Medicare's relationship with suppliers and departs from Medicare's practice of doing business with any qualified provider, because it is designed to limit the number of suppliers to those whose bids are at or under a certain amount.

Because of concerns that competitive bidding may prompt suppliers to cut their costs by providing lower-quality items and curtailing services, ensuring quality and access through adequate oversight is critical for the success of the competitive bidding program. In September 2004, GAO indicated that quality assurance steps could include monitoring beneficiary satisfaction, setting standards for suppliers, giving beneficiaries a choice of suppliers, and selecting winning bidders based on quality and the dollar amount of the bids. As competitive bidding expands, problems that beneficiaries might experience could be magnified. Therefore, continued monitoring of beneficiary satisfaction will be critical to identify problems with suppliers or with items provided to beneficiaries. As required in the MMA, GAO will review and report on the competitive bidding program's impact on suppliers and manufacturers and its effect on quality and access for beneficiaries.

[a]The quality standards are to be applied by one or more independent accreditation organizations designated by the agency. Accreditation is a process of certifying that health care organizations comply with specific standards and requirements.

Background

Medicare is the federal program that helps pay for a variety of health care services for about 44 million elderly and disabled beneficiaries. Most Medicare beneficiaries participate in Medicare Part B, which helps pay for certain physician, outpatient hospital, laboratory, and other services; medical equipment and supplies, such as oxygen, wheelchairs, hospital beds, walkers, orthotics, prosthetics, and surgical dressings; and certain outpatient drugs.[1] Medicare Part B pays for most medical equipment and supplies using a series of fee schedules. Generally, Medicare has a separate fee schedule for each state that includes most items, and there are upper and lower limits on the allowable amounts that can be paid in different states to reduce variation in what Medicare pays for similar items in different parts of the country. Medicare pays 80 percent of the lesser of the actual charge for the item or fee schedule amount for the item, and the beneficiary pays the balance. Beneficiaries typically obtain medical equipment and supplies from suppliers, who submit claims to Medicare on beneficiaries' behalf. Suppliers include medical equipment retail establishments and outpatient providers, such as physicians, home health agencies, and physical therapists. To handle claims processing for medical equipment and supplies, CMS contracts with durable medical equipment Medicare administrative contractors.

The Competitive Bidding Demonstration

Using its authority under the BBA, CMS conducted a competitive bidding demonstration to set Medicare Part B payment rates for groups of selected medical equipment and supplies.[2] CMS contracted with Palmetto Government Benefits Administrators (Palmetto) to administer the competitive bidding demonstration,[3] which was implemented in two

[1] Outpatient drugs covered under Part B include self-administered drugs, such as certain immunosuppressive and oral anticancer drugs, or drugs administered in conjunction with DME, such as inhalation drugs used with a nebulizer. A nebulizer is a device driven by a compressed air machine that allows the patient to take medicine in the form of a mist or wet aerosol.

[2] These groups were enteral nutrients, equipment and supplies, hospital beds and accessories, nebulizer inhalation drugs, manual wheelchairs and accessories, noncustomized general orthotics, oxygen contents, equipment and supplies, surgical dressings, and urological supplies.

[3] In this role, Palmetto was responsible for helping to plan the demonstration; educating beneficiaries, suppliers, and other stakeholders about the demonstration; soliciting and evaluating bids; processing claims; and responding to inquiries and complaints about the demonstration. CMS maintained oversight responsibility for the demonstration, reviewed all documents and Palmetto decisions, and made final design and policy decisions.

locations—the Polk County, Florida, metropolitan statistical area and parts of the San Antonio, Texas, metropolitan statistical area.

Two cycles of bidding took place in Polk County, with competitively set fees effective from October 1, 1999, to September 30, 2001, and from October 1, 2001, to September 30, 2002. One cycle of bidding took place in San Antonio, and competitively set fees were effective from February 1, 2001, to December 31, 2002. Bidding and implementation processes were similar at both locations. The demonstration ended on December 31, 2002.

The Competitive Bidding Program

In December 2003, the MMA required CMS to conduct competitive bidding for DME, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies on a large scale.[6] The MMA required that competition under the program begin in 10 of the largest metropolitan statistical areas in 2007, in 80 of the largest metropolitan statistical areas in 2009, and in other areas after 2009. The law established a new accreditation requirement for all Medicare suppliers of medical equipment and supplies and required CMS to develop financial and quality standards to use in selecting suppliers for the competitive bidding program. The law required CMS to take appropriate steps to ensure that small suppliers have an opportunity to be considered for participation in the competitive bidding program. CMS was required to establish a methodology for selecting bids from suppliers so that enough suppliers were selected to meet demand for competitively bid items within a given area. The law specified that at least two suppliers would be selected in each competitive area. The law also precluded judicial or administrative review of CMS's decisions to establish payment amounts, award contracts, designate areas for competition, select items and services, phase in implementation, and determine the bidding structure and number of suppliers selected under the competitive bidding program. The MMA required that an advisory committee be established to assist in carrying out the program.

To help implement the competitive bidding program, CMS published its notice of proposed rulemaking on May 1, 2006, and its final rule on April 10, 2007. CMS's final rule provided more detail on the agency's implementation steps. For example, the law specified that the agency could not award a contract to an entity unless it met applicable financial standards specified by the Secretary of HHS. In its regulation, CMS

[6]Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2254.

specified the financial documents that had to be submitted by suppliers to be considered as potential bidders. Similarly, while the law indicated that the agency needed to ensure that small suppliers had an opportunity to participate, the regulation sets out a process to include a certain number of small suppliers based on the percentage of those who bid and met all applicable requirements.

CMS established the initial round of bidding in 10 metropolitan statistical areas that included Charlotte, N.C.; Cincinnati, Ohio; Cleveland, Ohio; Dallas, Tex.; Kansas City, Mo.; Miami, Fla.; Orlando, Fla.; Pittsburgh, Pa.; Riverside, Calif.; and San Juan, P.R. On April 9, 2007, CMS opened the initial registration of suppliers for the first round of bidding and the bid period opened on May 15, 2007. As part of its program implementation for the first round, CMS conducted a supplier-education campaign, which included meetings, listserve announcements, a dedicated Web site, and a toll-free help desk. The bid period closed on September 25, 2007. CMS concluded bid evaluations and began the contracting process in March 2008, and the agency plans to announce the first round of winning suppliers in May 2008. Suppliers whose bids were disqualified because their bid did not meet program and bidding requirements will receive a letter informing them of the reason or reasons for their disqualification. After the program begins, suppliers whose bids were not chosen generally cannot receive Medicare payment for the competitively bid items in the metropolitan statistical areas included in the competitive bidding program. However, suppliers of certain rental items or oxygen that did not become suppliers in the competitive bidding program could continue to serve their existing Medicare customers. Suppliers that did not have bids chosen in the first round of the program may bid in the future rounds of competition. CMS said it plans to conduct a beneficiary-education campaign before the program goes into effect on July 1, 2008.

Competitive Bidding Could Reduce Program Payments by Creating an Incentive for Suppliers to Accept Lower Payment Amounts

Competitive bidding could reduce Medicare program payments by providing an incentive for suppliers to accept lower payment amounts for items and services to retain their ability to serve beneficiaries and potentially increase their market share. Using competition to obtain market prices in order to set payments for medical equipment and supplies is a new approach for Medicare that is fundamentally different than relying on fee schedules based on suppliers' historical charges to Medicare. Competitive bidding allows the market to provide information to CMS on what amounts suppliers will accept as payment to serve beneficiaries.

In its demonstration, CMS used a competitive bidding process to determine which suppliers would be included and the competitively set fees that they would be paid. From among the bidders, the agency and Palmetto selected multiple demonstration suppliers to provide items in each group of related products. Suppliers could submit bids and have winning bids for one or more groups of items. These suppliers were not guaranteed that they would increase their business or serve a specific number of Medicare beneficiaries. Instead, the demonstration suppliers had to compete for beneficiaries' business. All demonstration suppliers were reimbursed for each competitively bid item provided to beneficiaries at the demonstration fee schedule amounts. The new fee schedules were based on the winning suppliers' bids for items included in the demonstration. Any Medicare supplier that served demonstration locations could provide items not included in the demonstration to beneficiaries.

Evidence from the demonstration suggests that, for the items selected, competition helped set lower payment amounts and resulted in estimated program savings of $7.5 million. The demonstration's independent evaluators also estimated that beneficiaries saved $1.9 million. The demonstration provided evidence to health policy experts, including us and the Medicare Payment Advisory Commission, that competitive bidding for medical equipment and supplies could be a viable way for the program to use market forces to set lower payments without significantly affecting beneficiary access.[15]

About a year after the demonstration ended, the MMA required CMS to implement competitive bidding on a large scale and added requirements that suppliers would have to meet to participate in the competitive bidding program. The MMA also required the agency to develop quality standards and for suppliers to be assessed on those standards by accreditation organizations. In addition, the agency had to include a financial and quality assessment of suppliers as part of competitive bidding.

The competitive bidding program was structured to operate much like the demonstration. Suppliers submitted bids, along with other materials specified by CMS. The application required suppliers to submit 3 years of

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[15]The Medicare Payment Advisory Commission is an independent federal body established by the BBA to advise the U.S. Congress on issues affecting the Medicare program. Medicare Payment Advisory Commission, *Report to the Congress: Variation and Innovation in Medicare*, (Washington, D.C., 2003).

financial documents, including income statements, credit reports, and balance sheets. The review of the financial documents was used as part of the criteria for determining which bids to consider. The bidders had to have a valid Medicare supplier billing number and be accredited. Suppliers had to submit bids for one or more groups of items. CMS then evaluated the bids based on demand, capacity, and price and chose bids that were at or under a certain amount.

CMS estimates that the first round of its competitive bidding program will result in payment amounts that overall average 26 percent less than the current fee schedule amounts for the groups of items included, leading to savings for the Medicare program and its beneficiaries. CMS based its estimate on the price points suppliers submitted with their bids, weighted by market area and past utilization of items in each group. The estimated savings differed by groups of items, with the largest savings of 43 percent estimated for mail-order diabetic supplies.

Competitive bidding changes Medicare's relationship with suppliers. Competitive bidding is designed to reduce payments by allowing CMS to choose suppliers based on their bids—a change from the long-standing policy that any qualified provider can participate in the program. The competitive bidding process was designed to limit the number of suppliers to those whose bids were at or under a certain amount while ensuring that enough suppliers were included to meet beneficiary demand. In the demonstration, 50 percent to 55 percent of the suppliers' bids were selected. With few exceptions, only the suppliers whose bids were chosen could be reimbursed by Medicare for competitively bid items provided to beneficiaries residing in the demonstration area.[14]

Furthermore, competitive bidding could help reduce improper payments because it provides CMS with the authority to select suppliers, based in part on new scrutiny of their financial documents and other application materials. In November 2007, CMS estimated that 10.3 percent of Medicare payments made to suppliers of medical equipment and supplies were

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[14]Transition policies allowed beneficiaries to continue receiving oxygen equipment and supplies and nebulizer drugs from their original suppliers, regardless of whether the suppliers were included in the demonstration. However, the supplier had to accept the new fees set by the demonstration. Transition policies also allowed beneficiaries to maintain pre-existing rental agreements or purchase contracts with their suppliers of enteral nutrition equipment, hospital beds and accessories, and manual wheelchairs and accessories. These suppliers were paid under the normal statewide Medicare fee schedule for the duration of the rental period.

improper—more than double the percentage of improper payments to other Medicare providers. Providing additional scrutiny of suppliers gives CMS the opportunity to screen out those whose finances do not indicate that they are stable, legitimate businesses.

Adequate Oversight Is Critical to Ensure Quality and Access

Because of concerns that competitive bidding may prompt suppliers to cut their costs by providing lower-quality items and curtailing services, ensuring quality and access through adequate oversight is critical. Limiting the number of suppliers could potentially affect beneficiaries' access to quality items and services if there are an insufficient number to meet their needs. For some beneficiaries, having a choice of suppliers for some items and services could be important.

In our September 2004 report, we evaluated CMS's competitive bidding demonstration and recommended implementation actions for CMS to consider, including how to ensure access to quality items and services for beneficiaries. We indicated that quality assurance steps could include monitoring beneficiary satisfaction, setting standards for suppliers, providing beneficiaries with a choice of suppliers, and selecting winning bidders based on quality, in addition to the dollar amounts of bids.

The demonstration projects used several approaches for ensuring quality and services for beneficiaries, including monitoring beneficiary satisfaction and applying quality measures as criteria to select winning suppliers. During the demonstration, CMS and Palmetto used full-time, onsite ombudsmen to respond to complaints, concerns, and questions from beneficiaries, suppliers, and others. In addition, to gauge beneficiary satisfaction, independent evaluators of the demonstration fielded two beneficiary surveys by mail—one for oxygen users and another for users of other products in the demonstration. These surveys contained measures of beneficiaries' assessments of their overall satisfaction, access to equipment, and quality of training and service provided by suppliers. Evaluators reported survey results indicating that beneficiaries generally remained satisfied with both the products provided and with their suppliers. The independent evaluators identified some areas for concern, including a decline in the use of portable oxygen among users and the possible shift away from suppliers making home deliveries, which may have indicated that suppliers were visiting new medical equipment users less frequently to provide routine maintenance visits.

Because we considered careful monitoring of beneficiaries' experiences essential to ensure that any quality or access problems were identified quickly, we recommended that CMS monitor beneficiary satisfaction with the items and services provided under the new competitive bidding program. As competitive bidding expands and affects larger numbers of beneficiaries, problems such as those identified in the evaluations of the demonstration projects could become magnified. Therefore, continued monitoring of beneficiary satisfaction will be critical to identifying problems with suppliers or with items provided to beneficiaries. When such problems are identified in a timely manner, CMS may develop steps to address them. Such monitoring is important, not just when required by statute, but as part of an ongoing effort to ensure that the Medicare program is serving its beneficiaries effectively.

CMS agreed with our recommendation and stated that the agency would monitor the beneficiary satisfaction with the quality and services provided under the competitive bidding process. CMS also stated in the preamble of its final rule on accreditation of suppliers published August 18, 2000, that it expects that implementing medical equipment and supplies quality standards and accreditation will lead to increased quality of items and services throughout the industry. Furthermore, CMS stated that it plans to provide education to Medicare beneficiaries on the competitive bidding process using approaches such as press releases, fact sheets, and notices.

We will be assessing CMS's implementation of the competitive bidding program. As part of the MMA, we are required to review and report on the program's impact on suppliers and manufacturers and on quality and access of items and services provided to beneficiaries. As part of this review, we have been specifically requested to assess CMS's implementation of the program.

Concluding Observations

We believe that competitive bidding could reduce payments for both the Medicare program and beneficiaries. The independent evaluators estimated savings achieved in the demonstration, and CMS has projected reductions in payment amounts in its competitive bidding program for both Medicare and its beneficiaries. In addition, the new financial standards and accreditation process being implemented in conjunction with the competitive bidding program should help improve the financial viability and quality of medical suppliers providing services to Medicare beneficiaries. But competitive bidding also provides incentives that could affect access to services and lower quality of items and services provided to beneficiaries, which need to be monitored carefully.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or members of the Subcommittee may have.

Contacts and Acknowledgments

For further information regarding this testimony, please contact me at (202) 512-7114 or kingle@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Sheila Avruch, Assistant Director; Catina Bradley; Kelli Jones; Kevin Milne; Lisa Rogers; and Timothy Walker made contributions to this statement.

Related GAO Products

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Chairman STARK. Mr. Ryan.

STATEMENT OF THOMAS RYAN, AMERICAN ASSOCIATION FOR HOMECARE, AND PRESIDENT AND CHIEF EXECUTIVE OFFICER, HOMECARE CONCEPTS, INC.

Mr. RYAN. Good afternoon, Mr. Chairman, and distinguished Members of the Subcommittee. My name is Tom Ryan. I started in the home care industry as a respiratory therapist and have served patients in my community for 30 years. I'm the President and CEO of Homecare Concepts. It's a company I founded 20 years ago in Farmdale, New York, to provide respiratory and home medical equipment to people with medical conditions and disabilities. I appreciate the opportunity to testify about our very serious concerns regarding the competitive bidding program.

I am speaking today on behalf of the American Association for Homecare, where I recently served as Chairman and currently serve as a member of the executive Committee. Our members operate home care practices that will be impacted by the competitive bidding program. I am concerned about the problems that have plagued round one of this program. My company is scheduled to be in round two of the bidding program.

I will be blunt. This Medicare bidding program is a train wreck. But this program jumps off the tracks, the attitude of CMS is clearly let's go full steam ahead. The bidding program is poorly conceived, it's fundamentally flawed, and it does not account for the way home care providers currently compete for business. As a result of these flaws, the program has been plagued with problems since its inception. This program will drive people out of business. A large portion of high quality local home care providers will be driven out of business and they will no longer be able to serve the communities that they've been serving for years.

The real tragedy is the negative impact on the Medicare beneficiaries. Problems with the design and operation of the bidding program will seriously reduce beneficiary access, the quality of care, and products that beneficiaries receive today. The program is not the free market miracle that some have characterized it to be.

In light of these problems, the American Association for Homecare strongly urges Congress to immediately halt implementation of this program. We urge Congress to develop an alternative process that achieves not only accurate reimbursement rates for home medical equipment, but most importantly, ensures appropriate access to quality care for the Medicare beneficiaries.

The bidding program will drive thousands of qualified providers out of the marketplace, and as a consequence severely limit the services available to millions of seniors and people with disabilities. Providers currently compete on the ability to improve quality. That's what attracts referral sources to give us business. The new Medicare bidding program will stifle that competition.

There are multiple problems with various products subject to bid. I'll mention just a few. In the area of complex power wheelchairs, long-time consumers of customized wheelchairs will be forced to switch to new providers. For patients who rely on these specialty wheelchairs for daily activities, this is a drastic change.

In the diabetic treatment area, diabetic patients will be forced to switch to different monitoring systems and supplies, which has serious implications for patient compliance. The same point is true for cancer patients who depend on enteral nutrition for tube feeding. As a result of the new Medicare policy for home oxygen therapy, disruptive changes in the area of home oxygen therapy are scheduled to take place very soon. The transfer of ownership of oxygen equipment and the 36-month payment cap go into effect on January 1st, 2009. This will cause confusion among beneficiaries and will reduce the level and quality of services. New bidding rules only complicate these problems.

With respect to the impact on home care provides, 63 percent of the accredited home care providers submitted bids in round one, and they were disqualified. Most of these disqualifications were for technicalities. A 63-percent exclusion rate is totally unacceptable, and we feel is a serious breakdown in the bidding program.

Home medical equipment providers are overwhelmingly small to mid-size companies just like myself. We typically receive 50 percent of our business from Medicare. The loss in the ability to serve these patients will result in widespread layoffs and business failures.

The term "competitive bidding" is dead wrong. The bidding program will in fact radically reduce the number of accredited suppliers that are allowed to compete. The bidding program's widely touted savings are misleading. Small providers bid unreasonably low to have an opportunity to stay in the game, since the alternative was to go out of business. The fact that 64 percent of the suppliers that were offered contracts were small validates. We believe the extraordinary low-bid rates will be unsustainable over a 3-year contracting period, and any savings will be at the expense of services to the beneficiary.

Significant aspects of the development and implementation of this bidding program have been shrouded in secrecy. The lack of transparency, the unwillingness by CMS to share key information, mask deficiencies of the program and make it impossible to evaluate why CMS reaches various decisions. Moreover, CMS has rejected congressionally mandated working with the PAOC community. They have not worked with the PAOC community.

There are 33 business days before round one of this program takes effect. The program would be a historic change affecting as many as three million beneficiaries in the first phase alone, yet Medicare has not even announced who has won the bids yet, leaving the education of providers and beneficiaries till the last minute.

For this reason, the American Association for Homecare urges Congress to immediately halt the implementation of this program. The wide range of problems and questions about the program must be independently evaluated and an alternative process to determine payment rates for home medical equipment must be explored. The Association stands ready to work with members of this Committee and other Members of Congress immediately to address these issues.

In closing, I want to remind you that home care is part of the solution to Medicare. It's not part of the problem. Thank you for your invitation to speak, and I would welcome any questions that you have.

[The prepared statement of Thomas Ryan follows:]

Statement of Tom Ryan, American Association for Homecare

Good afternoon, Mr. Chairman and distinguished members of the Subcommittee. My name is Tom Ryan. I am a respiratory therapist and President and CEO of Homecare Concepts Inc., a respiratory and home medical equipment company based in Farmingdale, New York. I appreciate the opportunity to testify before you today about very serious concerns surrounding the Medicare DME competitive bidding program and the negative impact it will have on Medicare beneficiaries and homecare providers.

I am speaking today on behalf of the American Association for Homecare (AAHomecare) where I served as chairman during 2006 and 2007 and where I currently serve on its executive committee. AAHomecare is the national trade association representing both providers of durable medical equipment and manufacturers across the nation. The Association's membership reflects a broad cross-section of the homecare community including home medical equipment (HME) providers of all sizes operating in approximately 3,000 locations in all 50 states. I am also a member of the board of directors for the New York Medical Equipment Providers Association (NYMEP).

AAHomecare works to strengthen access to high quality care for millions of Americans who require home medical equipment, services and therapies in their homes. Many of our member providers operate health care facilities and businesses in areas that are subject to the Medicare competitive bidding program. I am scheduled to be in Round Two of bidding by virtue of serving beneficiaries in the New York metropolitan area, but I have heard and seen in detail the first-round problems that have plagued this high-profile program. I am well aware of the bidding program's anticipated effects on both Medicare beneficiaries and suppliers.

Summary

The Medicare bidding program is a poorly conceived and fundamentally flawed program that is now exhibiting many of the serious breakdowns that were predictable based on its failure to recognize and account for the true nature of the way home medical equipment is provided to Medicare beneficiaries. These breakdowns have been evident since the start of the Round One bidding process in early 2007, throughout the bid evaluation process, and right through the recent awarding of contracts. Design and operational problems in the bidding and contracting phase will seriously compromise beneficiary access and quality of care. The Association strongly urges Congress to immediately halt the implementation of this bidding program and develop an alternative process that achieves not only accurate reimbursement rates for home medical equipment but, most importantly, ensures good access to quality care for Medicare beneficiaries.

The current bidding program will drive thousands of qualified HME providers out of the Medicare marketplace. One of the consequences will be limitations on services available to millions of seniors and people with disabilities. Nearly two-thirds (63 percent) of accredited, qualified homecare providers that submitted bids have been disqualified in the first round of bidding. Moreover, such a dramatic reduction in the number of homecare facilities will result in reduced access to home providers and the quality of services that they provide if this bidding program moves forward in its current form. Errors and flaws that have emerged in Round One of bidding will be embedded in the program if CMS rushes to implement Round Two in 70 additional areas in the months ahead.

The Medicare Modernization Act mandated a competitive bidding program to establish market-based pricing for home-based equipment and care under Medicare. But because the bidding system will reduce the number of home medical equipment providers, it will needlessly eliminate thousands of qualified providers, reduce services to beneficiaries, and systematically dismantle the nation's homecare infrastructure.

HME providers are overwhelmingly small to mid-sized practices that typically receive about 40–50 percent of their business from Medicare patients. The loss in the ability to serve this patient population will result in layoffs and many business failures. The term "competitive bidding" is misleading because CMS is radically reducing the number of suppliers that compete in a given area.

The changes that will result from the bidding program will affect over three million beneficiaries who reside in Round One areas. CMS has indicated that if Round Two is implemented, approximately 50 percent of all Medicare beneficiaries requiring home medical equipment could be affected. The bidding program could also quickly affect all Medicare beneficiaries in the U.S. as early as January 1, 2009,

when CMS will have the authority to apply bid pricing in non-bidding areas. The ability of CMS to apply bid pricing to non-bidding areas, especially rural areas with hard-to-reach patients, is clearly not market-based.

For these reasons the Association urges Congress to immediately halt the implementation of this program until the wide range of problems and questions about the program can be independently evaluated and an alternative process to determine payment rates for home medical equipment can be explored. Without a pause in the implementation timeline to review serious concerns and examine alternatives, Medicare's home medical equipment benefit will be irreparably harmed.

Consequences of Bidding

Impact on Beneficiary Quality of Care

Many Medicare beneficiaries who reside in bidding areas will likely see: (1) a reduction in the level of services they receive; (2) lower quality items that may not be tailored to their specific needs; and, (3) disruptions in continuity of care as they are forced to switch providers.

Under the bidding program, suppliers are required to provide the same products to Medicare beneficiaries as they provide to non-Medicare patients, but only in situations where a physician specifically prescribes a certain product and brand. In all other cases, suppliers have the option to provide a range of products that fit within the physician's prescription. With the drastic reduction in reimbursement rates, there will be a diminution in the quality of goods and the level of service that suppliers have furnished in the past.

Additionally, CMS has also awarded contracts to suppliers who currently have no physical presence in bidding areas. These suppliers have the following options. They can: (1) quickly form subcontracting arrangements with local suppliers, or (2) attempt to open a new location(s) to service beneficiaries residing within a bidding area. In either case, suppliers will have to make these changes in the next 60 days because the program starts on July 1.

In the complex power wheelchair marketplace, there are a number of problematic areas that will impact quality of care. A contract winner who is not currently located in the bidding area could attempt to form subcontracting arrangements. However, the Medicare allowable set through bidding is unlikely to financially support both the contract supplier and the subcontractor. Also, CMS accrediting bodies cannot necessarily guarantee that "winning" suppliers use exclusively accredited subcontractors. In its final rule on bidding, CMS stated that it will "not evaluate subcontractors to determine if they meet the accreditation, quality, financial and eligibility standards because a subcontractor to a contract supplier cannot itself be a contract supplier and cannot submit claims under the Medicare DMEPOS Competitive Bidding Program." Moreover, these subcontracting suppliers could provide the beneficiary with a very inexpensive power wheelchair system that may not be as durable nor may it fully meet the beneficiary's needs, as complex power wheelchairs that are currently provided. Finally, CMS does not mandate that suppliers repair the complex power wheelchair they provide. Given the low payment rates for repairs, the Medicare beneficiary may very likely find him/herself unable to find a provider willing to repair the power wheelchair.

CMS made decisions in the diabetic arena that are likely to jeopardize disease management services to Medicare beneficiaries. In the diabetes treatment area, CMS did not ensure that all bidders played by the same rules. First, it did not define a formulary and it did not apply the rules of bidding equally to all bidders. As a result, CMS may have significantly limited beneficiaries' range of choices of diabetes monitoring systems and supplies. Second, by excluding retail providers from the bidding process, CMS distorted and clearly undermined the objectives of competitive bidding by allowing more than one reimbursement rate for the same product in an area. This was not envisioned by Congress. This unprecedented policy is anti-competitive. Unless winning suppliers are providing the same or equivalent products or services as are provided today, patients may now turn to retail stores for their supplies, where the cost is greater and there is no Medicare savings. We believe that CMS should establish one reimbursement rate for a product in an area regardless of where it is purchased, at a fair rate that allows choice so that beneficiaries do not have to switch their systems.

Over 20 million Americans currently live with diabetes, a serious and chronic disease. One in four Medicare patients suffers from diabetes and these beneficiaries account for 40 percent of Medicare spending. Given these statistics, it is imperative that we work to help patients more effectively manage their chronic disease. Reducing the likelihood that diabetes patients will be compliant in managing their disease should not be the bi-product of bidding.

Prior to bidding being implemented, significant policy changes have been slated to take effect that will impact home oxygen beneficiaries. The transfer of ownership of oxygen equipment and the 36-month payment cap—which both go into effect on January 1, 2009—are very likely to cause confusion with beneficiaries and adversely impact the level and quality of service beneficiaries have come to expect. These issues will only be magnified with bidding and its additional set of rules. For example, a beneficiary who is in his/her 31st month on oxygen therapy with an advanced oxygen system who moves to a new geographic area is unlikely to find an oxygen provider willing to furnish the same level of technology that the beneficiary was previously using.

There is also the real issue of suppliers being able to ramp up operations to meet significant new demand for medical equipment and services subject to bidding. While CMS has presumably selected enough suppliers to service an entire bidding area for each product category, contract suppliers are going to have to be prepared for a significant increase in demand for these items and services. Based on the information provided by CMS that identifies the number of contracts that were offered in each product category and each bidding area, contract suppliers could see an increase of 200–300 percent in the number of patients they are required to serve. Suppliers may be overwhelmed by the huge increase in volume, which their systems and infrastructure did not anticipate or may not be able to handle. This is especially true for suppliers who have never operated in bidding marketplaces prior to the implementation of this program. Contract suppliers that cannot meet demand are unlikely to provide the level of service that patients are accustomed.

These changes will also impact manufacturers who provide suppliers with lines of credit, which allow them, in turn, to purchase home medical equipment. These manufacturers will experience significant chaos in the credit market. Good providers who lost bids will become instant bankruptcy risks for manufacturer creditors because they have no way to anticipate the impact of bidding on suppliers and their ability to meet payment obligations. It will also be difficult for manufacturers to provide winning suppliers with the credit they are seeking given the significant payment cuts. Credit from financial institutions for winning suppliers who need to increase their operating capacity to meet increased demand also may not be readily available as the financial markets have recently made lending much more difficult. As a result, it will be the beneficiary who may not be able to receive the same quality of items and services that were previously provided due to credit pressures.

Impact on Beneficiary Access to Care

The Association is aware of some suppliers that were awarded contracts for certain product categories, which those same suppliers never before provided. In these circumstances, CMS has never outlined how it evaluated a supplier's self-reported plans to provide these new services. We also question how these suppliers could submit accurate bids for such services and items while also incorporating an unknown demand factor and operation costs into their bid calculation.

Consider the range of beneficiaries that will be impacted by bidding effective July 1:

- More than 220,000 Medicare beneficiaries who currently rely on home oxygen therapy may experience a disruption of their service if their provider does not elect to "grandfather" existing patients, and tens of thousands of new patients prescribed the therapy will have severely limited access from July 1, 2008 forward. As these beneficiaries assume ownership of their equipment in January 2009, they may have to switch providers in order to obtain portable oxygen.
- 143,000 beneficiaries currently receiving home-delivered diabetic supplies may be forced to switch providers by July 1 since there is no "grandfathering" provision. Small "winners" will be overwhelmed by the rush of patients to switch suppliers by CMS' deadline.
- 10,000 beneficiaries currently receiving home enteral nutrition therapy may be forced to switch providers by July since there is no "grandfathering" provision.
- 16,000 beneficiaries currently being treated at home for Obstructive Sleep Apnea (OSA) may have to switch providers as they assume ownership of their equipment under the Deficit Reduction Act (DRA).
- 25,000 elderly beneficiaries currently relying on hospital beds to remain at home may have to switch if their providers do not "grandfather" due to pricing in one or more markets.

Beneficiaries also are likely to face the prospect of coordinating care with multiple suppliers in bidding areas. Prior to bidding, a beneficiary's home medical equipment needs could be served by one supplier. Now, suppliers can only serve beneficiaries for items and services subject to bidding for which they have received a contract.

If a beneficiary needs a hospital bed, a walker and oxygen therapy, the beneficiary may require care from three separate suppliers due to the mechanics of the bidding program.

Few beneficiaries are aware that changes resulting from this program are imminent. If services and quality are reduced, if access is curtailed or beneficiary compliance diminishes—all likely outcomes from this program—Medicare costs will increase as patients require longer hospital stays, seek more frequent physician interaction and visit the emergency room.

Failure to Educate Beneficiaries, Referring Clinicians and Suppliers

CMS has touted an extensive list of steps it has taken to educate the supplier community about competitive bidding. Nevertheless, 63 percent of suppliers who attempted to participate were unable to navigate the bidding process and operational questions remain. Further, the supplier community, who has the most direct contact with existing beneficiaries that will be impacted by this program, has never been formally engaged by CMS to educate the beneficiary community on the changes that will result from bidding. To our knowledge, CMS has published only one pamphlet, in October 2007, to educate Medicare beneficiaries. This is for a program that is scheduled to go into effect in less than 60 days.

Now that there are "winners" and "losers" because of the program, "losing" suppliers have no incentive to educate beneficiaries and "winning" suppliers are consumed with the prospect of ramping up their operations to handle a significant increase in demand for services.

Once again it is the beneficiary that will suffer. Unfortunately, ensuring that three million beneficiaries in the 10 areas subject to bidding are educated on how the home medical equipment benefit will operate will be extremely difficult in the remaining days before this program goes into effect. Many Medicare beneficiaries who rely on or will need home medical equipment and services are the most frail within our health care system. Many do not have access to the internet. They are homebound. They are not able to attend public meetings like those held to educate beneficiaries about the Medicare Part D program.

Bidding Implementation Problems

The Medicare bidding program is expected to immediately impact more than 4,500 home medical equipment companies in the first ten metropolitan statistical areas. Ultimately, only 1,005 unique supplier companies submitted bids to CMS for consideration. Of that, 630 supplier companies were disqualified from consideration because of a failure to submit complete and accurate information—leaving a pool of only 375 companies for CMS to consider. Regardless of whether supplier packages were deemed complete or incomplete, we do not believe that any program where more than 60 percent of suppliers were disqualified should be considered a success and should move forward. These statistics point to a failure by CMS to properly educate suppliers about the bidding program and flaws within the internal bid submissions review process.

The lack of supplier participation can be traced back to the initial bid submission period in May 2007. Suppliers in the 10 metropolitan areas subject to bidding immediately encountered a wide range of significant problems.

Suppliers found that the bid submission system was primitive, cumbersome and fraught with problems resulting in excessive data input time and loss of submitted data. Frequently, the system was non-operational and inaccessible.

The problems faced by suppliers during the bidding window were so significant that CMS extended the bidding window three times (two one-week delays followed by a 60-day delay). Ultimately, however, we believe that some suppliers were unable to navigate the program and were unable to participate in the program.

More procedural and operational flaws that threatened the integrity of the entire program became more readily apparent when CMS began informing suppliers whether they won a contract on March 21. These flaws include, among others: (1) the Competitive Bidding Implementation Contractor's (CBIC) inappropriate rejection of qualified bids due to misplaced or overlooked documentation that was properly and timely submitted by suppliers; (2) inappropriate disqualification of bids due to purported "financial stability" reasons, which neither the CBIC nor CMS has ever explained during or after the bidding process; (3) a seemingly arbitrary process regarding how the CBIC or CMS used providers' self reporting capacity to determine how many winning suppliers were needed for each market; and (4) extremely minimal information disclosed in terms of the calculation of the winning bid amounts and related results.

The original "request for bids" rules on the CBIC's web site stated that the CBIC will inform suppliers of any deficient documentation; the original RFB rules said

that, "beginning 10 business days before the bidding window ends, suppliers will be notified if there is any missing hard copy attachments." These rules were in place as of May 2007, and upon which suppliers relied as they navigated the cumbersome and confusing bid process. However, on September 13 (just prior to the closing date of (Sept. 25, 2007), the CBIC revised this RFB rule without any type of notice to the bidding community.

Equally troubling, especially in light of an extraordinary disqualification rate of 63 percent, is that CMS has never delineated a process at any time in the development or implementation of this program by which suppliers who were disqualified would be able to have their cases reviewed. Subsequent to the mass disqualification of suppliers on March 21, the CBIC initially informed suppliers who questioned their disqualification that their cases would be reviewed for accuracy within 30 days. Recently, the CBIC has sent e-mail communication to some of these suppliers indicating that it would not be able to meet its stated review period. For others, the CBIC has just reaffirmed the original "incorrect" disqualification and left these suppliers, who have proof that they have been wrongly disqualified, with no avenue for a proper review of their supporting information.

Home Medical Equipment Supplier Impact

The Association believes that the Medicare bidding program will radically change the HME marketplace if implemented in its current form. CMS will selectively contract with only approximately 300 unique supplier companies in the first 10 metropolitan areas under the fee-for-service program. CMS' own statistics have shown that approximately 4,500 unique companies reside in these 10 bidding areas. This would indicate that CMS intends to contract with approximately 7 percent of existing home medical equipment companies. Even if we only account for the unique companies that took part in the program—1,005 companies—CMS is still threatening the financial viability of 70 percent of the otherwise qualified and accredited suppliers in the current homecare marketplace.

The integrity of contract suppliers may also become a question since some suppliers who participated in the program submitted bids based on the assumption that they would be awarded contracts for multiple product categories subject to bidding. If, for example, a supplier submitted its bids expecting to be a contract supplier for multiple product categories but only "won" a contract for one product category, the supplier's long-term sustainability may be in question.

Homecare has been shown to be the most cost-effective and patient preferred type of care provided to beneficiaries. As baby boomers retire and become eligible for the Medicare program, demand for home medical equipment is likely to increase. These beneficiaries will prefer the advancements in technology that allow them to live full lives in the home setting. Arbitrarily limiting the number of homecare companies that the market will support should be viewed as selective contracting, not competitive bidding.

Savings Questionable

The bidding program designed by CMS is fatally flawed and its widely touted savings are misleading. Smaller suppliers were fearful that larger suppliers had a competitive advantage in the bidding system due to the ability of these larger suppliers to negotiate volume pricing with manufacturers. As a result, smaller suppliers believed they could only remain viable by bidding at levels that were extraordinarily low, but assumed that larger supplier bids would reflect accurate (higher) pricing and would increase the final Medicare single payment amount, thus, rationalizing payments.

Essentially, small suppliers bid unreasonably low to have an opportunity to "stay in the game" since the alternative is to go out of business. The fact that a large percentage of suppliers offered contracts, 63 percent, were small suppliers validates this theory. Because so many small suppliers bid so low, these bidders came close to meeting the capacity projections; preventing many of the larger firms' bids from being considered. We believe the extraordinarily low bid rates will be unsustainable over a three-year contracting period.

The argument that the pricing levels established through bidding are indicative of market pricing is unfounded. The bid system established an elaborate "game" with skewed incentives, resulting in prices that are not reflective of market pricing; but instead were based upon a desperate need to "stay alive" through the bid program.

We anticipate that beneficiaries in the bid areas will receive lesser quality items and reduced services. Also problematic will be beneficiary disruption and confusion that will lead to additional program costs in the form of longer hospital stays, more frequent physician visits and care sought in emergency rooms. None of these factors

has ever been identified by CMS in its presentation of savings that can be achieved through bidding.

Lack of Government Transparency

The development and implementation of the bidding program have been shrouded in secrecy. The lack of transparency masks deficiencies of the program and makes it impossible to evaluate fully the way CMS reached its various decisions at every stage of the process. CMS' unwillingness to share basic information about the program raises serious questions about any future rounds of the program with respect to fair supplier selection and patient access to quality suppliers.

CMS has not shared meaningful bidding data nor the methodology and criteria used to establish new Medicare payment rates and the criteria by which suppliers were evaluated. By refusing to release critical data, CMS is impeding an open assessment and dialogue with the public.

How did CMS evaluate the financial stability of providers? How did CMS review a supplier's self-reporting capacity to meet the market's need? Did CMS properly calculate the single payment amount? What criteria did CMS use to evaluate bids and determine whether a bid was a "bone fide" one? What process did CMS use to re-evaluate the bidding packages of suppliers who believe they were inappropriately disqualified from the program? These and other questions still remain unanswered and threaten the integrity of the bidding program.

Recommendations

Due to the flaws, errors and questions that have plagued Round One, and will certainly carry through to Round Two, we urge Congress to immediately halt the implementation of this bidding program. The Association supports the implementation of a rational, alternative process to determine Medicare pricing for DME items and services.

AAHomecare stands ready to work with members of this Committee and other members of Congress as early as today to address these complex challenges and ensure the provision of cost-effective and quality homecare to deserving Medicare beneficiaries.

Chairman STARK. Thank you.
Mr. Thomas.

STATEMENT OF PETER W. THOMAS, ESQ., CO–CHAIR, CONSORTIUM FOR CITIZENS WITH DISABILITIES HEALTH TASK FORCE

Mr. THOMAS. Thank you, Mr. Chairman. My name is Peter Thomas and I'm being so bold today as to try to represent the voice of the Medicare beneficiary through the Consortium for Citizens with Disabilities. CCD is a coalition of 100 national disability-related organizations and includes some of the major disability groups in the country, including the Brain Injury Association of America, the United Cerebral Palsy Associations, the National Multiple Sclerosis Society and many others.

Let me just take a moment to say that we've talked a lot about devices and products today. I just need to bring home to the Committee how vital these devices and services and items really are to beneficiaries across the board, across the Medicare Program, but especially for those with long-term needs with severe disabilities, with chronic conditions. These items and services and related devices are a lifeline to independent living and to functionality and to health care, good, solid health care.

In addition to the senior population, of course, the Medicare program covers over six million people below the age of 65 that are only on the program because they have disabilities that permit them—or that do not permit them to work. I hope that this Com-

mittee and CMS really takes this into account in implementing the program.

DMEPOS items and services disproportionally impact people with disabilities. This is a relatively vulnerable population in the Medicare program and assistive devices really mean a great deal for function and health care. The CCD groups have opposed competitive bidding since the beginning, in 1997 with the demonstration projects, in 2003 when the MMA passed, and of course now less than 2 months before it's being implemented.

Under the current fee schedule, price is a constant, and suppliers compete on a range of other variables, including good service to patients, including being responsive to referral sources and physicians, and exercising good business practices. That's what competition is currently in the Medicare system for this benefit. When price becomes the sole determinant of who gets the contract, all of those other provisions become secondary. So, the CCD opposes competitive bidding for three main reasons: One, it will reduce choice, two, it will reduce quality, and three, it will reduce access.

As to choice, choice of supplier, the competitive bidding program clearly reduces the choice of suppliers as a large number of longstanding, high quality providers did not receive bids. Thousands and thousands of people with disabilities will wake up on July 1st and have disruptions in their provider-patient relationships, many of whom will not know the first thing as to how to address those new needs.

Two, in terms of brand names. People with disabilities and chronic conditions often use brand names because they have particular needs or they have particular preferences that a particular brand of DME item or service will really address. So we are very concerned with shrinking margins and with lesser providers that you're going to have a restriction in the number and breadth of devices covered under the program.

Number two is quality. We believe that there will be in fact a race to the bottom in the area of quality with respect to competitive bidding. You know, the ability to choose and move from provider to provider under the current system is an important quality assurance mechanism. If a beneficiary doesn't have a major interest in being restricted in their provider choice and would like to save some on copayments, they can join the Medicare Advantage plan. But if they're in the fee-for-service plan, we feel strongly that they should maintain—have the right to choose their provider and the services that that provider provides.

In terms of access, we also believe that the competitive bidding program will dramatically limit access to not only the number of suppliers, and in fact cause additional need to travel long distances and the like.

So, we have a series of recommendations. The first would be, and our hope is to simply repeal or eliminate the competitive bidding program. We believe there are mechanisms that are currently in place that CMS has to adjust prices if they deem them unreasonable, and to use those existing authorities to adjust reimbursement levels when necessary. If competitive bidding is not repealed or eliminated, we do think that Congress should delay round one because of the concerns that I've raised in my testimony.

If in fact that is not possible, certainly round two should be delayed, because round two is where you are able to learn what occurred in round one and hopefully apply those lessons learned.

We do think that exempting specific, uniquely fitted and individualized items and services are extremely important, and so we do support the Medicare Access to Complex Rehabilitation and Assistive Technology Act, H.R. 2231, which would exempt seating, positioning, mobility devices and speech-generating devices from competitive bidding.

Finally, let me also say that we think that there should be an opt-out provision for beneficiaries to choose to opt out of competitive bidding and simply pay the 20 percent of the fee schedule amount, at least in the first or second year of this program, to act as a real safeguard and a safety measure to ensure compliance with quality care.

There is one other recommendation before I end, and that simply is for CMS to create a separate toll-free number and have an ombudsperson or people who are well qualified to answer these questions and address the concerns that we are sure are going to come to them on July 1st and beyond.

Thank you very much.

[The prepared statement of Peter W. Thomas follows:]

Statement of Peter W. Thomas, Health Task Force Co-Chair, Consortium for Citizens with Disabilities

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

Thank you for this opportunity to testify on Medicare's competitive bidding program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS"), scheduled to begin being implemented in less than two months from today.

My name is Peter Thomas and I am an attorney with the law firm of Powers, Pyles, Sutter and Verville, P.C. I am here today representing the Consortium for Citizens with Disabilities ("CCD") Health Task Force. The CCD is a coalition of over 100 national disability-related organizations working together to advocate for Federal public policy that ensures the self determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society. CCD members include the National Multiple Sclerosis Society, the Brain Injury Association of America, United Cerebral Palsy Associations, and United Spinal Association, to name a few. The CCD Health Task Force focuses on health care policy from the perspective of people with disabilities and chronic conditions and, as such, I am testifying today to bring forth the views of Medicare beneficiaries, particularly those with significant health care needs.

I am also here as an individual with personal experience with a disability. My 34 years walking on artificial legs has demonstrated the vital role that assistive devices can play in the health, function, rehabilitation, and independent living of people with disabilities, including Medicare beneficiaries. And it is important to remember that in addition to seniors, the Medicare program serves the health care needs of over six million beneficiaries below the age of 65 who have become Medicare eligible due to a disability that is severe enough to prevent them from working.

Many CCD member organizations opposed the Medicare DMEPOS competitive bidding program since 1997 when the competitive bidding demonstration projects were authorized by statute. The current competitive bidding program was authorized in the Medicare Modernization Act of 2003 ("MMA") over the objection of many disability-related groups. Those same groups, and more, remain deeply concerned about the impact of this program on Medicare beneficiaries. This is because we believe this program disproportionately impacts and unfairly places at risk some of Medicare's most vulnerable beneficiaries—individuals with disabilities and chronic conditions. We fail to see why Congress and the Administration would single out vital assistive devices and technologies under the Medicare *fee-for-service* program to be provided by the lowest bidder when other benefits are not exposed to this potentially harmful practice.

The hallmark of the Medicare fee-for-service program is patient choice of provider/supplier. Accessing the provider of choice is an important quality assurance mechanism, as any beneficiary can simply choose another qualified provider if their current provider is not meeting their needs. The current fee schedule makes price a constant variable and makes suppliers compete for Medicare beneficiaries by providing excellent service, meeting patients' needs, establishing reliable and long-standing relationships with physicians who refer patients to suppliers. When competitive bidding is employed, the sole variable becomes price, while service, patient satisfaction, patient choice, and access are presumed to be equivalent from one supplier to another. As such, the fee schedule amount of an assistive device may decrease, but so will the quality of care.

This is particularly important to beneficiaries who have significant health care needs on an ongoing basis. If a beneficiary is not concerned about choice of provider and would prefer to spend a little less on copayments under Medicare Part B, they are free to choose to enroll in a Medicare Advantage plan. Policymakers who have concerns about the restrictions and disincentives in Medicare Advantage plans should not be in favor of extending these same principles to the Medicare fee-for-service program, as the current law will do.

To date, the competitive bidding program has been largely viewed as a provider/supplier issue centered on the price that Medicare pays for durable medical equipment and supplies ("DME"). (Although competitive bidding generically applies to the DMEPOS benefit, all prosthetic limbs and most orthotic braces are exempt from competitive bidding due to the fact that they are highly customized to the patient and require significant clinical services.) Although CCD and other consumer groups have long opposed competitive bidding, it has been the DME/home care industry that has been most vocal on this issue. However, as we now begin to see the details of implementation of this program and the real-life impact that these enormous changes in the benefit will have on beneficiaries, we feel that the consumer voice needs to be amplified.

CMS is about to begin a massive experiment and individuals with disabilities and chronic conditions are the unwitting participants. The public awareness of this program is extremely low and we are convinced that many thousands of Medicare beneficiaries with long term disabilities and chronic conditions will awake on July 1st to find that they no longer have access to their trusted DME supplier. These beneficiaries will have to start anew with another supplier, one who may be less convenient and less familiar with beneficiaries' specific needs. We as consumers must underscore at this point that assistive devices and technologies are not interchangeable, luxury items, but, instead, are essential tools with which we create independent lives. In our opinion, experimenting with the quality of and access to these devices is risky and simply not reasonable.

That being said, we are *not* opposed to adjusting Medicare reimbursement levels for items and services to make them more reasonable for beneficiaries. And we recognize the benefits to consumers of lower reimbursement levels in the form of reduced co-payments. However, there are currently mechanisms in place for CMS to adjust reimbursement levels, such as the inherent reasonableness process. It is our strong belief that the modest decreases in co-payments that will result from the competitive bidding program simply do not outweigh the price that beneficiaries with disabilities and chronic conditions will pay in the form of reduced access, quality, and choice.

Although CCD does not support competitive bidding, we do support the Medicare Modernization Act's requirements that DMEPOS suppliers become accredited and meet certain quality standards in the provision of care. These requirements are vital to help ensure that all beneficiaries receive the highest quality devices and technologies to meet their medical and functional needs.

CCD Concerns with Competitive Bidding for DMEPOS

Although there has been a significant lack of beneficiary education from CMS leading up to the roll out of this program, the CCD Health Task Force is beginning to hear from members and numerous other stakeholders regarding the potential threats to assistive devices and technologies under this program. As a result, we have objectively analyzed the program and I will summarize our current concerns.

Decrease in the Quality of Devices, Products, and Technologies: CMS estimates that, on average, the price Medicare will pay suppliers for the targeted products is 26% lower than current payment rates. These dramatic price reductions provide disincentives to suppliers to offer the highest quality devices and products. The likely decrease in the quality of assistive devices and technologies, especially highly individualized or complex devices and technologies, threatens the ability of the beneficiary to be as functional and independent as possible. Additionally, the use of im-

proper equipment could result in related medical complications (e.g. bed sores, shoulder injuries) for the individual and the costs of treating these complications will likely diminish significantly the cost savings from competitive bidding. Furthermore, because many private payors take their reimbursement cues from Medicare, we expect that individuals with private insurance will eventually face many of the same quality issues as Medicare beneficiaries when competitive bidding is implemented.

Access to Related Services: Often individuals with significant disabilities such as spinal cord injuries, cerebral palsy, multiple sclerosis, and amyotrophic lateral sclerosis ("ALS"), require assistive devices that must be fitted and/or programmed to meet their individual needs. In addition, technology assessments, home evaluations, and other specialized services are regularly performed in order to ensure that the appropriate equipment is provided. Suppliers often have 24-hour hotlines for emergency service and strive to maintain quick turn-around times on repairs. With the significant decrease in reimbursement to suppliers for the competitively bid items and, from what we understand, the inexperience of many of the potential contract suppliers to provide the benefits they have been selected to provide, CCD members are extremely concerned that these related services will either be restricted or no longer available to consumers.

We would like to make clear that time-consuming services provided to beneficiaries such as fittings, refittings, evaluations, programming, repairs, etc., are not optional services, but instead, are vital to the safe and effective use of many assistive devices and technologies.

Access to Suppliers: It is our understanding that suppliers, when bidding, offered CMS an estimate of the percentage of the population in a metropolitan statistical area ("MSA") that they believed they would be able to serve. CMS then used these estimates to determine which suppliers would be offered Medicare contracts without, apparently, conducting any independent verification of these supplier estimates. It is also our understanding that CMS expected approximately 15,000 bids to be submitted for the first round of the program but received just 5,000. We also understand that across the 10 MSAs, CMS only offered 1,300 contracts to suppliers, even though they expected to award 9,000. We expect the result to be a significant decrease in the number of suppliers available to Medicare beneficiaries and CCD is very concerned that this decrease, combined with the unverified manner in which CMS has determined the number of suppliers necessary in each MSA, will result in serious access problems.

For example, Lisa is a Medicare beneficiary with quadriplegia who uses a custom seating and positioning system to promote proper posture and preserve skin integrity while using her wheelchair. She currently receives services at a specialized seating clinic, often the only setting where a beneficiary in need of specialized seating systems can be served properly. However, the suppliers that serve the seating clinic were not offered a contract by CMS under the competitive bidding program and, as a result, Lisa will loose access to the comprehensive "team" approach available only at this type of clinic. Instead, she will have to travel ten miles farther to the next appropriate supplier who will not be able to provide services using this team approach. It is important to note that many individuals will also face the new and difficult burden of physically accessing a new supplier who is located much farther from their home or in a location that is more difficult for them to access. For individuals with severe disabilities, this new burden cannot be underestimated.

Impact on Beneficiary-Supplier Relationships: Many Medicare beneficiaries may wake up on July 1st to find that they can no longer purchase items from their supplier with whom they have worked for many years. Many suppliers have detailed knowledge of their patients' disabilities and related conditions, and a history of providing them with the most appropriate devices to meet their needs. These long-standing beneficiary-supplier relationships could be considered one of Medicare's best defenses against fraud and abuse and an important quality indicator; however, many of these relationships will be broken as a result of the competitive bidding program.

For example, John, a power wheelchair user, had a spinal cord injury when he was in high school and has been going to the same supplier, located just four blocks from his home, for over 20 years. This supplier has detailed knowledge of his disability and related conditions such as prior decubitus ulcerations, contractures, and "overuse syndrome" in his shoulders, all conditions secondary to his disability. As a result, this supplier has a history of providing John with the most appropriate wheelchair and related accessories to meet his changing needs. However, because this supplier was not selected as a contractor in the Medicare competitive bidding program, as of July 1st, John will have to start all over with a new supplier. The new supplier has no historical knowledge of his particular disability and related

needs, does not carry the specific brand of wheelchair he has used for years, and is located more than five miles from John's home.

Access to Brand Name Devices: Individuals who use assistive devices will tell you that consumer preference for a specific brand is an important factor when determining the most appropriate device. Competitive bidding will force many individuals to switch to new suppliers who may not offer the same brands of devices that they are accustomed to using. A forced substitution in brand could significantly impact the functional level of an individual, thereby impacting their health and functional status.

CCD's Policy Recommendations to Congress

Congress intended the competitive bidding program to be phased-in over a several-year period by 2010. Unfortunately, because CMS fell behind in the implementation of the first round, the agency has accelerated the implementation of the second round, to be implemented in 70 MSAs next year, in order to meet the 2010 statutory deadline. This accelerated timeline means that CMS will be expanding competitive bidding virtually nationwide with very little data on the impact of the program on Medicare beneficiaries. It also leaves little time for Congress to act to protect consumers.

For the reasons stated in this testimony, we urge Congress to eliminate DMEPOS competitive bidding entirely so as not to subject Medicare beneficiaries, especially those with disabilities and chronic conditions, to a system that compromises access, quality, and choice. CMS currently has at its disposable mechanisms to adjust prices when Medicare reimbursement levels are deemed unreasonable, and it should use those existing authorities to adjust reimbursement levels when necessary.

If competitive bidding proceeds to be implemented, we urge Congress to delay implementation of the first round of DMEPOS competitive bidding until significant flaws in the selection process and number of suppliers are addressed and until safeguards are in place to protect the consumer.

We urge Congress and CMS to delay the second round of DMEPOS competitive bidding in order to allow CMS and stakeholders appropriate time to assess and address the impact of the first round on all Medicare beneficiaries, especially people with disabilities and chronic conditions.

We strongly support Congressional efforts to exempt items from competitive bidding that must be uniquely "fitted" and individualized for the specific user. CCD supports the Medicare Access to Complex Rehabilitation and Assistive Technology Act (H.R. 2231/S. 2931), legislation to carve-out complex assistive technology and devices such as seating, positioning, and mobility devices and speech generating devices from the competitive bidding program, with the goal of protecting appropriate access.

We urge Congress and CMS to allow beneficiaries with disabilities and chronic conditions to keep their current supplier under the competitive bidding program in order to ensure continued quality and choice of supplier. One method may be to allow Medicare beneficiaries to "opt-out" of the competitive bidding network and continue accessing their supplier of choice at the Medicare DMEPOS fee schedule amount. Quality would be ensured as consumers would have the right to pay less under competitive bidding or continue to pay a higher copayment with their long-standing suppliers. Considering the potential for significant disruptions in service if the first round of competitive bidding proceeds on July 1st, this proposal seems imminently reasonable, at least for the first year or two of implementation.

We urge CMS to establish a separate toll-free number and ombudsperson for beneficiaries to use regarding competitive bidding questions and concerns. Consumers will have numerous and important questions regarding the changes in the DMEPOS benefit and a specific toll-free number and access to an ombudsperson are important safeguards in implementation of this program. Such a dedicated toll-free number would also allow Congress to more accurately monitor the impact of competitive bidding on Medicare beneficiaries.

Reforming Competitive Bidding in a Difficult Fiscal Environment

CCD usually does not address Medicare reimbursement issues involving providers and suppliers unless the policy proposals at issue impact access to quality care. DMEPOS competitive bidding is such a case and, in this difficult fiscal environment and with the implementation date for competitive bidding looming, we offer the following thoughts.

First, any and all alternatives to competitive bidding that are considered by Congress, if designed to be budget neutral, should ensure that beneficiaries are not harmed by compromised access, quality, and choice.

Second, if Medicare DME fee schedule adjustments are to be made as an alternative to competitive bidding, we would argue that such adjustments must be confined to the range of DME items subject to competitive bidding, rather than an across-the-board fee schedule adjustment. For instance, prosthetic limbs, orthopedic braces, and a range of other DMEPOS items are not included in competitive bidding and they should not be affected if Congress decides to adjust certain fee schedules to make budget neutral changes to competitive bidding.

Conclusion

CCD is very concerned that competitive bidding will significantly threaten access to and quality of assistive devices and technologies that are essential components of the health and independence of individuals with disabilities and chronic conditions. We call on Members of Congress and the Administration to delay implementation of the program and initiate appropriate safeguards to ensure that individuals with disabilities are not harmed by the upcoming changes in this important benefit.

I thank you for this opportunity to testify before the subcommittee and welcome your questions.

Chairman STARK. Thank you, Mr. Thomas.

Dr. Hoerger.

STATEMENT OF THOMAS J. HOERGER, PH.D., SENIOR FELLOW, RESEARCH TRIANGLE INSTITUTE (RTI) INERNATIONAL

Mr. HOERGER. Mr. Chairman and Members of the Committee, I am pleased to appear before you today. My name is Thomas Hoerger. I'm a Senior Fellow at RTI International and also Director of the RTI-University of North Carolina Center of Excellence in Health Promotion Economics. RTI International is an independent nonprofit research organization that performs research for the U.S. Government and private sector clients. Since 1991, I have led a series of studies on competitive bidding for Medicare Part B services. All these studies were funded by CMS. In one of these studies, my colleagues and I evaluated the impact of Medicare's competitive bidding demonstration for DMEPOS. After the evaluation, I led an RTI project to provide technical assistance to CMS on the design and implementation of the DMEPOS competitive bidding program. That project ended in August 2007, thus I'm aware of the general design of the bidding program, but I have no direct knowledge of specific issues relating to how the suppliers were selected.

Today my comments focus on our evaluation of the DMEPOS competitive bidding demonstration as well as on the potential value of using competitive bidding to set prices for DMEPOS. The demonstration project took place in two metropolitan statistical areas between 1999 and 2002 with two rounds of bidding taking place in Polk County, Florida and one round of bidding taking place in San Antonio, Texas.

We evaluated the impact of the demonstration on Medicare expenditures, beneficiary access to care, quality of care, competitiveness of the market, and the reimbursement system. Our full evaluation report was included as part of the required report to Congress on the demonstration project and is available for downloading from the RTI website.

Briefly, we reached the following conclusions. Competitive bidding produced lower prices, leading to lower allowed charges for

the Medicare Program and reduced copayments by beneficiaries. We estimated that the demonstration reduced Medicare allowed charges by 9.4 million or 19 percent.

The demonstration had relatively little effect on beneficiary access, quality and product selection. Beneficiaries remained as satisfied with their suppliers as they were before the demonstration. The estimated reductions in program expenditures exceeded the estimated costs of implementation.

Because the demonstration reduced allowed charges, supplier revenues had to fall, and that result was probably viewed negatively by suppliers in general. Overall, we concluded that the impacts of the demonstration were largely positive.

Looking more broadly at the use of competitive bidding for DMEPOS, the basic rationale for competitive bidding is relatively simple. Ask suppliers how much they are willing to accept in payment for providing DMEPOS to beneficiaries. Then offer contracts to those suppliers offering the lowest prices, ensuring that enough suppliers who are accredited are selected to serve all beneficiaries. Thus, in principle, competitive bidding gives suppliers strong incentives to reveal their underlying costs and meet accreditation and quality standards and allow CMS to select suppliers who can provide DMEPOS products most efficiently, thereby using program funds and taxpayer dollars in the most prudent way.

Although the basic rationale for competitive bidding for DMEPOS is simple, implementing competitive bidding is more complicated. As they say, the devil is in the details, and there a lot of details when it comes to implementation. In the interest of time, I will only mention three of the most important issues.

First and foremost is quality. The biggest concern with competitive bidding is that after offering low prices, winning bidders will provide low-quality products and little or no service to beneficiaries. Congress and CMS have attempted to address this issue by requiring accreditation for all DMEPOS suppliers serving Medicare, both in competitive bidding and in other areas. With this accreditation, specific quality standards are also imposed for each product category.

Finally, multiple suppliers were selected in each bidding area and product category. Thus, suppliers will need to provide quality in order to attract beneficiaries.

Second, in selecting winning bidders, CMS must take great care to ensure that enough suppliers are selected to serve the Medicare beneficiaries in an area. This requires CMS to carefully balance beneficiary access and program expenditures, because selecting more suppliers would cause the winning bid to increase. Or, conversely, if you try to keep the winning bid to low, access may be reduced. It is important to achieve the right balance.

Third, suppliers should be treated fairly in the bidding process. This means providing adequate information about the program and the bidding process and general information about how bids will be evaluated. However, CMS cannot release the proprietary bids of individual suppliers.

I would be happy to answer any questions. Thank you for your time.

[The prepared statement of Thomas J. Hoerger follows:]

Statement of Thomas J. Hoerger, Ph.D., Senior Fellow, Research Triangle Institute (RTI) International

Mr. Chairman and Members of the Committee, I am pleased to appear before you today to provide you with information on research I have performed on Medicare competitive bidding programs for Part B services.

My name is Thomas J. Hoerger. I am a Senior Fellow at RTI International and also director of the RTI-University of North Carolina Center of Excellence in Health Promotion Economics. RTI International is an independent, nonprofit research organization based in North Carolina that performs research and technical services for the U.S. Government and private sector clients.

Since 1991, I have led a series of six studies on the design, evaluation, and implementation of competitive bidding for Medicare Part B services. All of these studies were funded by the Centers for Medicare & Medicaid Services (CMS). In one of these studies, my colleagues and I evaluated the impact of Medicare's competitive bidding demonstration for DMEPOS. After that evaluation, I led an RTI project to provide technical assistance to CMS on the design and implementation of the DMEPOS Competitive Bidding Program. That project ended on August 31, 2007; thus, I am aware of the general design of the bidding program but I have no direct knowledge of specific issues relating to how suppliers were selected in the first round of bidding for the program.

Today, my comments focus on our evaluation of the DMEPOS competitive bidding demonstration as well as on the general potential value of using competitive bidding to set prices for DMEPOS.

Evaluation of the DMEPOS Competitive Bidding Demonstration

The demonstration project took place in two metropolitan statistical areas between 1999 and 2002, with two rounds of bidding taking place in Polk County, Florida and one round of bidding taking place in San Antonio, Texas. We evaluated the impact of the demonstration on (1) Medicare expenditures, (2) beneficiary access to care, (3) quality of care, (4) competitiveness of the market, and (5) the reimbursement system. Data sources for the evaluation included site visits and telephone discussions with key demonstration participants, focus groups, surveys of beneficiaries and providers, bid analysis, and claims analysis.

Our full evaluation report was included as part of CMS's required Report to Congress on the demonstration project and is available for downloading at http://www.rti.org/pubs/DMEPOS—final-report.pdf. Briefly, we reached the following conclusions.

- Competitive bidding produced lower prices, leading to lower allowed charges for the Medicare program and reduced copayments by beneficiaries. We estimated that the demonstration reduced Medicare allowed charges by $9.4 million, or 19%. Medicare program expenditures fell by about $7.5 million, and beneficiary payments fell by about $1.9 million.
- The demonstration had relatively little effect on beneficiary access, quality, and product selection. Beneficiaries remained as satisfied with their suppliers as they were before the demonstration.
- The estimated reductions in program expenditures exceeded the estimated costs of implementation.
- Because the demonstration reduced allowed charges, supplier revenues had to fall, and that result was probably viewed as a negative effect by suppliers in general. As expected, demonstration suppliers gained market share as a group, while nondemonstration suppliers lost market share.

Overall, we concluded that the impacts of the demonstration were largely positive.

The Rationale for Competitive Bidding

Looking more broadly at the use of competitive bidding for DMEPOS, the basic rationale for competitive bidding is relatively simple: ask suppliers how much they are willing to accept in payment for providing DMEPOS to beneficiaries. Then offer contracts to those suppliers offering the lowest prices, ensuring that enough suppliers who are accredited and follow predetermined quality standards are selected to serve all beneficiaries. Thus, in principle, competitive bidding gives suppliers strong incentives to reveal their underlying costs and meet accreditation and quality standards, and allows CMS to select suppliers who can provide DMEPOS products most efficiently, thereby using program funds and taxpayer dollars in the most prudent way.

Although the basic rationale for competitive bidding for DMEPOS is simple, implementing competitive bidding is more complicated. As they say, the devil is in the

details, and there are a lot of details when it comes to implementation. In the interest of time, I will only mention 3 of the most important issues.

First and foremost is quality. The biggest concern with competitive bidding is that after offering low prices, winning bidders will provide low-quality products and little or no service to beneficiaries. Congress and CMS have attempted to address this issue by requiring accreditation for all DMEPOS suppliers serving Medicare, both in competitive bidding areas and in other areas. With this accreditation, specific quality standards are also imposed for each product category. Finally, multiple suppliers were selected in each bidding area and product category. Thus, suppliers will need to provide quality in order to attract beneficiaries.

Second, in selecting winning bidders, CMS must take great care to ensure that enough suppliers are selected to serve the Medicare beneficiaries in an area. This requires CMS to carefully balance beneficiary access and program expenditures, because selecting more suppliers will cause the winning bid to increase. It is important to achieve the right balance.

Third, suppliers should be treated fairly in the bidding process. This means providing adequate information about the program and the bidding process and general information about how bids will be evaluated. However, CMS cannot release the proprietary bids of individual suppliers.

Additional Details on the Evaluation

The Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS was conducted by the University of Wisconsin-Madison Center for Health Systems Research and Analysis and RTI International under CMS Contract No. 500–95–0061. Authors of the final evaluation report included Sara Karon, Thomas Hoerger (Project Director), Shulamit Bernard, Kevin Tate, Richard Lindrooth, Teresa Waters, and Kay Jewell.

Selected key results from the evaluation, taken from the Executive Summary, include the following:

Medicare Expenditures

- In Polk County, Round 1 demonstration prices were lower than the existing Florida fee schedule for at least 90% of all items in 4 product categories. For surgical dressings, most demonstration prices were higher. Almost all Round 2 demonstration prices were lower than the Florida fee schedule.
- In San Antonio, demonstration prices were lower than the existing Texas fee schedule for all items in 4 product categories. In the remaining category, more than half of the demonstration prices were lower.
- For most demonstration items, the demonstration did not have a statistically significant effect on utilization.
- Assuming that the demonstration had no impact on utilization, we estimate that the demonstration reduced allowed charges in Polk County by $4.7 million during its 3 years of operation. We estimate that the demonstration reduced allowed charges in San Antonio by $4.6 million during its 23 months of operation.
- Combining savings from both sites, we estimate that the demonstration reduced allowed charges by nearly $9.4 million (19.1 percent). Medicare expenditures (defined as allowed charges less co-payments and deductibles) fell by about $7.5 million, and beneficiary payments fell by about $1.9 million.

Beneificiary Access

- Beneficiary survey data showed few statistically significant demonstration impacts on access-related survey measures in Polk County and San Antonio. This suggests that the demonstration had little overall impact on beneficiary access in these sites.
- In Polk County, most demonstration suppliers chose to serve every zip code in Polk County. Similarly, in San Antonio, most suppliers chose to serve all three counties in the demonstration area.
- The transition to demonstration prices and suppliers passed relatively smoothly in Polk County and San Antonio. The smooth transitions appeared to be related to the existence of transition policies and the willingness of nondemonstration oxygen suppliers to continue serving their patients. As a result, there was relatively little disruption of existing relationships between suppliers and beneficiaries during the transition.
- Our Polk County beneficiary survey analysis detected a statistically significant decline in the provision of portable oxygen equipment and an increase in conserving device usage among new users under the demonstration. We also detected a decline in maintenance visits among new users of medical equipment in the demonstration area. Other statistically significant impacts in Polk County included changes in the ways beneficiaries order and receive their equip-

ment, as well as declines in some types of training for urologicals and surgical dressings users.
- In contrast, beneficiary surveys in Texas indicate that the demonstration did not have a significant impact on portable oxygen and conserving device use in San Antonio, nor was there a decline in maintenance visits for new users of medical equipment.
- To further evaluate the impact of the demonstration on portable oxygen use in Polk County, we analyzed claims data. This analysis indicates that the demonstration had a negative and statistically significant impact on the percentage of new oxygen users who received portable oxygen, especially during Round 2. However, the negative impact was smaller in magnitude than the impact suggested by the beneficiary survey.
- Referral agents who ordered equipment and supplies for their patients reported a few problems with access during the first months of the demonstration. Agents later became more familiar with demonstration rules and demonstration-eligible suppliers, and began using suppliers with whom they were comfortable. In general, referral agents did not think that the demonstration had a negative impact on beneficiaries' access to care, but the agents believed this was due to the additional responsibilities they assumed to ensure access and quality.

Quality and Product Selection
- Users of oxygen and other medical equipment in Polk County and San Antonio were highly satisfied with their experiences with their DMEPOS suppliers. Survey data show that overall satisfaction ratings were high before the demonstration and remained high 1 year after implementation.
- Survey data indicate that quality of DMEPOS products and services was high before and after the demonstration in both Polk County and San Antonio. There were few statistically significant demonstration impacts on quality-related survey measures, suggesting that the demonstration had little overall impact on quality.
- During site visits to Polk County in Round 1, concerns were raised about the quality of urological supplies. Some suppliers believed that—partly through supplier inexperience—prices in Round 1 were set too low. Prices rose in Round 2, and a urological supplier with a strong reputation was added as a demonstration supplier.
- During site visits to San Antonio, referral agents reported a number of issues related to wheelchair service provided by some demonstration suppliers. Some suppliers did not provide the level of service expected by referral agents in terms of equipment setup and delivery, initial fitting and adjustments, and responsiveness to problems. Agents responded by cutting referrals to these suppliers and by taking increased responsibility for ensuring quality service to their patients.
- San Antonio suppliers reported on product selection in a supplier survey. Most suppliers reported little change in the products they supplied before and after the demonstration began.

Competitiveness of the Market
- Thirty suppliers submitted a total of 71 bids in Polk County in Round 1 of the demonstration. Sixteen suppliers, both large and small firms, were selected as demonstration suppliers. Twenty-six firms submitted a total of 52 bids for the four product categories in Round 2, and 16 suppliers (62 percent) were awarded demonstration status. The number of firms submitting bids for urological supplies in Round 2 fell from 9 to 7, and the number of suppliers bidding for surgical dressings fell from 8 to 4. These product categories had the fewest Round 1 demonstration suppliers.
- Entry into and exit from the market were still possible in the presence of competitive bidding. Half of the Round 2 demonstration suppliers in Polk County also had demonstration status in Round 1, but half did not.
- Seventy-nine firms submitted a total of 169 bids for the five product categories in San Antonio. Overall, 65 percent of the suppliers that submitted bids won demonstration status in at least one product category.
- As a group, demonstration suppliers gained market share during the demonstration, whereas nondemonstration suppliers lost market share. In product categories where there were transition policies that allowed nondemonstration suppliers to continue to serve existing customers, the increase in market share for demonstration suppliers occurred gradually.
- The demonstration had relatively little effect on market concentration.

- As expected, individual suppliers generally gained market share if they were demonstration suppliers and lost market share if they were nondemonstration suppliers. Some demonstration suppliers in Polk County, gained substantial market share. However, being named as a demonstration supplier did not guarantee increased market share. In San Antonio, many demonstration oxygen suppliers had little or no increases in market share due to the fact that many of the largest suppliers in the predemonstration period were granted demonstration status.

Reimbursement System

- From an operational standpoint, CMS and Palmetto GBA were able to successfully implement the demonstration project. The project team was able to effectively solicit, collect, and evaluate bids; educate suppliers, referral agents, and beneficiaries; monitor quality and behavior; and administer claims throughout the demonstration.
- Although the overall implementation was successful, not everything went perfectly. A flaw in the weighting system used to evaluate bids in Round 1 of the Polk County demonstration led to higher prices in the surgical dressings category. In San Antonio, CMS delayed the start of the demonstration by 1 month, and delivery of the demonstration directories was delayed until very close to the actual starting date. Such problems were relatively minor and reflect one of the benefits of conducting demonstration projects: the ability to learn from the demonstration and apply the lessons if the demonstrated system is adopted on a wider scale.
- For the entire demonstration, CMS and Palmetto GBA costs of implementation totaled about $4.8 million between 1995 and 2002. The costs of implementing the demonstration were nearly 50 percent lower than the projected $9.4 million reduction in Medicare allowed charges associated with the demonstration.

Administered Fee Schedules for DMEPOS

Previously, Medicare used an administered fee schedule to set DMEPOS prices. The fee schedule was based on historical DMEPOS prices, with periodic updates for inflation, occasional price fees mandated by legislation, and occasional price reductions for items that were believed to be overpriced. Since the fee schedule was established, DMEPOS products have experienced great technological change, utilization has increased dramatically, labor costs have risen, and the cost of delivering many DMEPOS products has increased. As a result, there is little reason to believe that the administered fee schedule reflects the prices that would be set in a perfectly competitive market for DMEPOS products.

It can be difficult to adjust an administered fee schedule to reflect market forces. The administrators of the fee schedule lack information to know when costs have risen or fallen and they typically lack authority to make changes to the fee schedule. Suppliers have no incentive to say when the costs of providing DMEPOS have fallen, and a strong incentive to say that costs have risen. The Government Accountability Office (GAO) has conducted a series of studies concluding that Medicare pays too much for selected DMEPOS items. The industry has responded, sometimes with good reason, that the prices cited by the GAO do not reflect the full cost of serving Medicare beneficiaries.

Chairman STARK. Thank you. We're going to just question for about 10 minutes and we'll at that point happily have to adjourn the hearing. But I have one principal question.

I want to thank the witnesses for their patience and their willingness to provide us with this information, but I'm afraid, Mr. Ryan, that you're stuck. I don't think you'll get any quarrel from anybody on the dais today that the system is flawed. As a matter of fact, somewhere between flawed and lousy, and it's unimportant. Fault in that case is a useless concept.

But to the extent that we're going to change it, the Congressional Budget Office, who is a fiddler to whom we have to dance here, has said that a 1-year delay in round one would lose $3.5 billion in projected savings, or as we look at, if we're going to have a 1-year delay, we've got to come up with $3.5 billion in savings. Over 5

years, the current program is north of $6 billion over the next 5 years.

Now we ain't going to take that out of kiddies' health insurance, and we ain't going to take that out of the hospitals, and the doctors already gave at the office. So, my question to you is, is your industry prepared to have their fees adjusted downward to the extent of $3.5 billion over five or $6 billion more likely, if we get rid of this bidding process? That's the bind you're in.

Mr. RYAN. Mr. Chairman, I understand we're in a PAYGO environment and we need—we're in a PAYGO environment, and we do need to look at alternatives. As I said, yes, the industry is ready and willing today to sit and talk about alternatives.

We gave at the office quite a bit as well. If you look at the history of what this industry has given back——

Chairman STARK. I've heard it.

Mr. RYAN [continuing]. Has been significant. We also have to understand that the 26 percent savings that Mr. Weems talks about is unrealistic. That is just unrealistic.

Chairman STARK. Mr. Ryan, all that's well and good. We have to—if we are going to solve this legislatively, and we may not, we're going to have come up with 6 billion bucks over 5 years. You know the drill. The question is, is your industry willing—we just write a bill. We say, Mr. Secretary, cut out the bidding and come up with the cost savings through adjusting price structure. Are you willing to live with that?

Mr. RYAN. Mr. Chairman, the industry is willing to work with this Committee, and, yes, we're willing to see if we cannot come up with a savings projection.

Chairman STARK. Uh-uh. Uh-uh. Uh-uh. Six billion bucks. I mean, I know you're willing to work with us. My question is, are you willing to come up with the $6 billion——

Mr. RYAN. Yes.

Chairman STARK [continuing]. To get rid of the bidding system?

Mr. RYAN. Yes.

Chairman STARK. Great. That's—I think we can do business. Mr. Camp.

Mr. THOMAS. May I please make a statement?

Chairman STARK. Pardon?

Mr. THOMAS. Mr. Chairman, may I please say a word?

Chairman STARK. Sure.

Mr. THOMAS. The CCD usually does not engage in finding offsets and talking about payment issues as they impact suppliers, but in this instance, because these discounts are so deep, wherever it does impact access, we do tend to speak up. The only two principles that we would suggest that if you do move in that direction, that we would hope that whatever discounts or offsets are found obviously do not impact quality choice and the beneficiary, and also that they be——

Chairman STARK. We'd direct the Secretary to do that and Dr. Hoerger would make a plan to see that it didn't happen.

Mr. THOMAS. Fair enough.

Chairman STARK. Mr. Camp.

Mr. CAMP. Well, I—thank you, Mr. Chairman. Frankly, you asked the exact question I was going to ask, and I know we're run-

ning up against a vote, and so I don't think I need to repeat it, but that is exactly my concern in terms of what we do with the PAYGO problem that we're facing. I was going to ask in a more open-ended way how we might get out from under this, and I think that's something that you can provide us later, but the fact that you've admitted your willingness to support this PAYGO result I think is important. So, I thank you for stepping up. I thank you all for your testimony, and I would just yield back.

Chairman STARK. Mr. Tiberi.

Mr. TIBERI. Thank you, Mr. Chairman. To Mr. Ryan, what's the average size of your members of your association employee-wise?

Mr. RYAN. Our average member probably is in about a $3 million range.

Mr. TIBERI. How many employees?

Mr. RYAN. Are you talking about my company or the association? I'm sorry.

Mr. TIBERI. The members of the association, companies like yours that are members of the association.

Mr. RYAN. Well, my particular company has 52 employees. We're a $6 million company.

Mr. TIBERI. How many members are members of the association, how many companies?

Mr. RYAN. Five hundred.

Mr. TIBERI. What's the average? Is 52 the average or 25?

Mr. RYAN. I would say it's in the area of 30 to 40 perhaps. Eighty-5 percent are considered small, and according to——

Mr. TIBERI. Thank you. Thank you.

Mr. RYAN [continuing]. Five million. I'm sorry, sir.

Mr. TIBERI. Would you say that 100 percent of the members of this organization share your concern? Ninety percent? Seventy-five percent?

Mr. RYAN. I believe that 100 percent of the members of my association share the concerns about national competitive bidding and the access to quality. I do believe that, sir.

Mr. TIBERI. Thank you. I know we have limited time. Thank you, Mr. Chairman, for holding this hearing today.

Chairman STARK. I want to thank my colleagues and the witnesses. It's arguably a program where the numbers are significant but there seems to be some impetus to see if we can't revise the system. I want to thank you, Mr. Ryan, because we are faced with rules. Mr. Camp and I might have written the rules differently, but we didn't write them. There is no other way. We're boxed into this. It would be better if CMS would cooperate with us, but they may not, in which case we're faced with meeting these budgetary requirements. We'll do our best, and I'm not sure of the legislative schedule being what it is this year that we'll be able to resolve it this year. Hopefully, we will because the more it expands across the country, the bigger the problem it will be. So I'd like to find a way to see if we couldn't get a resolution to this early on. Appreciate your industry. I appreciate representation of the consumers. It's important. GAO has got some more information to give us. We'll look forward to that. Dr. Hoerger, I think you're going to probably get another consulting contract before this is all done.

We'll put you back to work, and thank our witnesses for participating, and the hearing is adjourned.

[Whereupon, at 3:31 p.m., the hearing was adjourned.]

[Questions for the Record follow:]

Questions posed by Mr. Johnson to Kathleen M. King

Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 23, 2008

Kathleen M. King
Director
Health Care
U.S. Government Accountability Office
441 G. Street, NW
Washington, DC 20548

Dear Ms. King:

As a follow up to the Ways and Means Health Subcommittee Hearing on DME Competitive Bidding on Tuesday, May 6, 2008; please respond to the following Questions for the Record.

Questions from Rep. Sam Johnson

(1) In your testimony you say that adequate oversight of competitive bidding is critical. Does GAO have specific recommendations on what oversight is needed to ensure continued access and quality to beneficiaries?

GAO
Accountability * Integrity * Reliability
United States Government Accountability Office
Washington, DC 20548

June 9, 2008

The Honorable Pete Stark
Chairman
The Honorable Dave Camp
Ranking Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable Sam Johnson
House of Representatives

Subject: Follow-up Question for the Hearing Record

After the May 6, 2008 House Ways and Means Health Subcommittee hearing on durable medical equipment competitive bidding, GAO was asked whether it had specific recommendations on what oversight is needed to ensure continued access and quality to Medicare beneficiaries. It was also noted that we had stated in our testimony before the Subcommittee that adequate oversight of competitive bidding is critical.

Adequate oversight of CMS's competitive bidding program (CBP) is needed to ensure that Medicare beneficiaries have continued access to quality durable medical items and supplies and that the process for selecting winning bidders is transparent and ensures supplier choice. As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, GAO will review and report on CBP's impact on suppliers and manufacturers and its effect on quality and access for beneficiaries. Because our work is ongoing, we do not have specific recommendations at this time.

CMS agreed with the recommendation from our 2004 report to monitor beneficiary satisfaction, which can be used as a tool to help ensure that beneficiaries continue to have access to quality medical items and services under the CBP. CMS has plans to survey beneficiaries to measure their level of satisfaction with the services they received before the program began and after the program is operational. CMS also plans to track the number of CBP questions and requests for information that are received through the 1-800-MEDICARE help line and the State Health Insurance Assistance Programs. We also stated in our 2004 report that selecting winning suppliers based on quality measures, in addition to the dollar amounts of their bids, is a way for CMS to ensure that beneficiaries have access to quality medical items and services.

Kathleen M. King
Director, Health Care

Questions posed by Mr. Johnson to Thomas J. Hoerger

Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 23, 2008

Thomas J. Hoerger, Ph.D.
Senior Fellow, RTI International
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park, NC 27709-2194

Dear Dr. Hoerger:

As a follow up to the Ways and Means Health Subcommittee Hearing on DME Competitive Bidding on Tuesday, May 6, 2008; please respond to the following Questions for the Record.

Questions from Rep. Sam Johnson

(1) From your experience with the implementation of the demonstration project, do you believe CMS was able to successfully implement the demonstration project in the two cities? What were some of the implementation issues that were identified in this demonstration? How were they rectified in the demonstration project and were the lessons learned applied to the roll out of Round 1?

(2) The major concerns we are hearing from suppliers surround the submission of financial disclosure documents. Did you encounter any of these types of problems in the demonstration project? Any advice on how to rectify the current predicament CMS finds themselves in?

Questions from Rep. Sam Johnson

(1) From your experience with the implementation of the demonstration project, do you believe CMS was able to successfully implement the demonstration project in the two cities? What were some of the implementation issues that were identified in this demonstration? How were they rectified in the demonstration project and were the lessons learned applied to the roll out of Round 1?
(2) The major concerns we are hearing from suppliers surround the submission of financial disclosure documents. Did you encounter any of these types of problems in the demonstration project? Any advice on how to rectify the current predicament CMS finds themselves in?

Responses

(1) Based on our evaluation, we concluded that CMS was able to successfully implement the demonstration project in the two sites. As noted in the Executive Summary of our Final Evaluation Report,

- "From an operational standpoint, CMS and [its contractor] Palmetto GBA were able to successfully implement the demonstration project. The project team was able to effectively solicit, collect, and evaluate bids; educate suppliers, referral agents, and beneficiaries; monitor quality and behavior; and administer claims throughout the demonstration.

- Although the overall implementation was successful, not everything went perfectly. A flaw in the weighting system used to evaluate bids in Round 1 of the Polk County demonstration led to higher prices in the surgical dressings category. In San Antonio, CMS delayed the start of the demonstration by 1 month, and delivery of the demonstration directories was delayed until very close to the actual starting date.

- Such problems were relatively minor and reflect one of the benefits of conducting demonstration projects: the ability to learn from the demonstration and apply the lessons if the demonstrated system is adopted on a wider scale. CMS modified the bid weights before Round 2 bidding in Polk County, and the Round 2 prices of surgical dressings declined. Similarly, the delays in San Antonio signaled the importance of including adequate time to evaluate bids and approve winners and the need to provide timely delivery of demonstration directories."

More broadly, we concluded that the overall impacts of the demonstration were largely positive. Again quoting from the Executive Summary of the Final Evaluation Report:

"Based on our evaluation, we believe that the overall impacts of the demonstration were largely positive. Competitive bidding produced lower prices, leading to lower allowed charges for the Medicare program and beneficiaries. We found that the demonstration had relatively little effect on beneficiary access, quality, and product selection. Beneficiaries remained as satisfied with their DMEPOS suppliers during the demonstration as they were before the demonstration. There is a cost to implementing the demonstration, but the estimated reductions in program expenditures exceeded the estimated costs of implementation. By definition, if the demonstration reduced allowed charges, supplier revenues had to fall, and that result will likely be viewed as a negative impact by suppliers in general. Still, the demonstration produced the expected results among suppliers; demonstration suppliers gained market share as a group, while nondemonstration suppliers lost market share."

Although I was not involved in the evaluation of bids and selection of winners for the current program, I believe that most of the lessons from the demonstration were incorporated in the design of the program. The original timeline for bidding and selection of winners in the program allowed sufficient time for notification of winners and the timely delivery of supplier directories. However, delays in the announcement of winners may have pushed back the delivery of supplier directories.

(2) Our evaluation team did not directly review the financial documents submitted by bidders during the demonstration project (they were reviewed by the implementation contractor's Bid Evaluation Panel and CMS staff). However, from our evaluation, we are aware that assessing financial status was challenging in the demonstration project. Overall, the assessments resulted in a relatively wide range of scores ranging from poor (scores less than 70 out of 100) and average (70-79 points) to good (80-89 points) and excellent (>90 points). Suppliers in the financially competitive range with quality ratings of good to excellent were selected with no conditions. Several suppliers in the financially competitive range with average quality rankings were selected conditionally; these suppliers were required to meet specific conditions to become demonstration suppliers. In San Antonio, seven suppliers were not initially selected as demonstration suppliers. Under demonstration rules, these suppliers were allowed to file for reconsideration. Six suppliers did so, and ultimately five achieved demonstration status after providing supplemental information and/or correcting deficiencies.

Collecting and assessing financial information under the program rules is even more challenging because (a) the volume of bids is much higher in the program because more sites are included, and (b) the legislation requires that contracts cannot be awarded to suppliers that fail to meet financial requirements. Financial documents are generally large and variable in format; consequently, they cannot easily be loaded into a single automated format that can be tested electronically for completeness and accuracy. I suspect that the large number of bids led to the decision to not notify bidders who did not

submit all of the required documents, while the legislative requirement led to these bids being disqualified.

There are several options for rectifying the current situation:

(a) The CBIC could notify all suppliers who have not submitted complete financial documents.

(b) The CBIC could conduct a preliminary ranking of bids and contact any suppliers who are likely to be in the competitive range but have incomplete financial documents. These suppliers would be given a short time to provide financial documentation (or show that they had previously submitted the documentation). The initial competitive range would be based on capacity estimates for those suppliers with full financial documentation; therefore, the competitive range might be reduced as the notified suppliers provided their documentation.

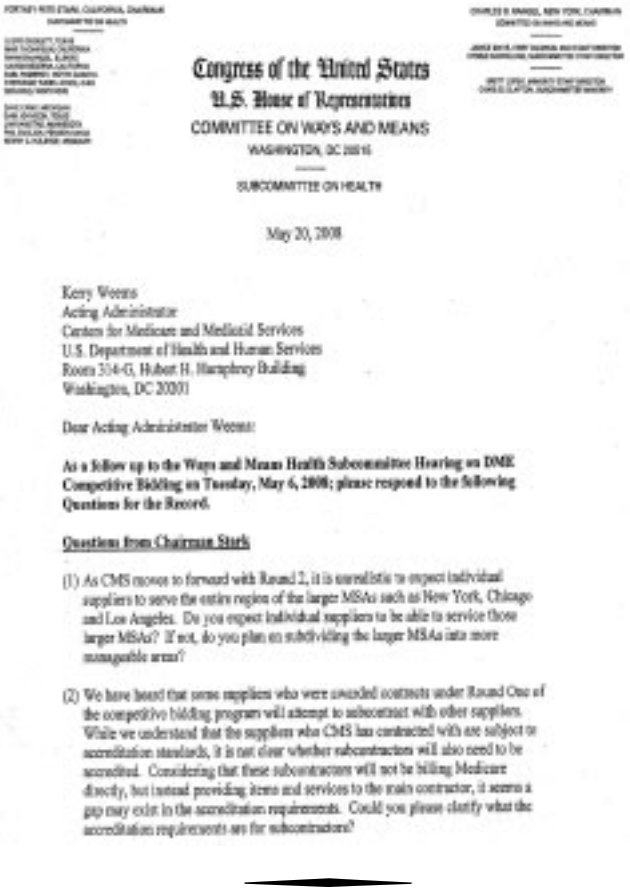
(c) CMS could simplify the requirements for financial documentation, creating specific forms that could be automatically verified for completion. However, it might be difficult to confirm that the information included is correct.

(d) CMS could make no changes, and rely on the first round experience convincing suppliers to take greater care in submitting the financial documents.

Of these options, I believe that (b) would best balance fair treatment for suppliers with administrative burden.

A remaining conceptual issue is whether there is enough evidence linking the required financial information to the ability of suppliers to stay in business for the duration of the contract. The point of the financial requirements is to ensure that CMS contracts with suppliers who will not go out of business. Although it is plausible that the financial variables are associated with future performance, we don't have clear evidence on how strong the association is. For example, if a supplier's financials are "poor", we don't know whether its probability of going out of business during the next 3 years is closer to 100% (clearly warranting disqualification), 50% (disqualification is questionable), or 20% (probably not warranting disqualification). Until we have better information on the relationship between the financial variables and bankruptcy, it might be better to allow such suppliers to receive contracts, but discount their estimates of capacity. This would lead to more suppliers receiving contracts.

Questions for the record posed by Mr. Stark, Mr. Kind, and Mr. Johnson to Kerry Weems



Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 20, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

Dear Acting Administrator Weems:

As a follow up to the Ways and Means Health Subcommittee Hearing on DME Competitive Bidding on Tuesday, May 6, 2008; please respond to the following Questions for the Record.

Questions from Chairman Stark

(1) As CMS moves to forward with Round 2, it is unrealistic to expect individual suppliers to serve the entire region of the larger MSAs such as New York, Chicago and Los Angeles. Do you expect individual suppliers to be able to service those larger MSAs? If not, do you plan on subdividing the larger MSAs into more manageable areas?

(2) We have heard that some suppliers who were awarded contracts under Round One of the competitive bidding program will attempt to subcontract with other suppliers. While we understand that the suppliers who CMS has contracted with are subject to accreditation standards, it is not clear whether subcontractors will also need to be accredited. Considering that these subcontractors will not be billing Medicare directly, but instead providing items and services to the main contractor, it seems a gap may exist in the accreditation requirements. Could you please clarify what the accreditation requirements are for subcontractors?

Questions from Rep. Ron Kind

(1) How will CMS determine which rural areas will be exempted from the competitive bidding program? Has that determination already taken place? If not, when will it be conducted and what specific information will CMS rely on to make such a determination?

(2) What factors will CMS use to determine when and how it will exercise its authority under Social Security Act (SSA) § 1834(a)(1)(F)(ii) (for DME), SSA § 1834(h)(1)(H)(ii) (for off-the-shelf orthotics), and SSA § 1842(s)(3)(B) (for enteral nutrients, supplies, and equipment), which allow the agency to apply prices from winning bids in other MSAs around the country to rural areas?

Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 23, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

Dear Acting Administrator Weems:

As a follow up to the Ways and Means Health Subcommittee Hearing on DME Competitive Bidding on Tuesday, May 6, 2008; please respond to the following Questions for the Record.

Questions from Rep. Sam Johnson

(1) In the Final Rule issued April 2, 2007, CMS permits physicians to furnish certain types of competitively bid items without submitting a bid and winning a contract. These items include crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and infusion pumps, but do not include off the shelf orthotics. However, the rule does allow physical and occupational therapists to provide off the shelf orthotics to their patients without participating in competitive bidding because "we have determined that these items would ordinarily be furnished as an integral part of occupational or physical therapy services." Why is there a separate standard for physicians and physical therapists and is there a legitimate concern that this may compromise the ability of physicians to provide medically necessary orthotics to their patients. Why did CMS choose to create a separate standard for physicians and is the agency considering a way to correct this problem?

(2) The Final Rule requires physicians to become accredited in order to supply any orthotics to their patients in the Medicare program. Due to the cost and paperwork required it is likely that many physicians will likely choose not to become accredited, this will then raise some questions about how beneficiaries will receive medically necessary orthotics. In a separate rule relating to Medicare DMEPOS supplier standards released on January 25, 2008, the agency proposes

an across-the-board prohibition on suppliers sharing a practice location with other suppliers—including physicians and other health care practitioners. Physicians at times need to dispense medically necessary DMEPOS items immediately to a Medicare beneficiary—like stabilizing braces, or immobilizing devices. Isn't there a concern that this proposed rule, when considered in conjunction with the new requirements on physicians under competitive bidding, could deny Medicare beneficiaries the ability to receive these medically necessary items when they need them?

Additional Written Questions
Ways & Means Health Subcommittee Hearing
On
"DME Competitive Bidding"
May 6, 2008

Chairman Stark

1. As CMS moves forward with Round 2, it is unrealistic to expect individual suppliers to serve the entire region of the larger MSAs such as New York, Chicago and Los Angeles. Do you expect individual suppliers to be able to service those larger MSAs? If not, do you plan on subdividing the larger MSAs into more manageable areas?

   Answer: We agree that it is important to apply the bidding rules in a way that is practical for suppliers, and ensures beneficiaries' access to services. The statute requires that we expand the program to an additional 70 of the largest MSAs in the country in 2009. As part of this expansion, CMS has selected the three largest MSAs (New York, Chicago, and Los Angeles) to participate in Round 2 of the competitive bidding program.

   While we have selected these MSAs for Round 2, we have not yet identified the actual competitive bidding areas (CBAs) within these large metropolitan areas. For Round 1, we identified actual bidding areas by zip codes in order to ensure a cohesive market area within each MSA that did not include noncompetitive areas of low population density (relative to the rest of the MSA). CMS expects to perform this same type of analysis as we look at New York and the other areas selected. As a result, the actual CBA may be smaller than the entire MSA, as permitted under the competitive bidding statute. We expect the competitive bidding program will result in real savings for beneficiaries in New York and the other areas selected for both Rounds 1 and 2.

2. We have heard that some suppliers who were awarded contracts under Round 1 of the competitive bidding program will attempt to subcontract with other suppliers. While we understand that the suppliers who CMS has contracted with are subject to accreditation standards, it is not clear whether subcontractors will also need to be accredited. Considering that these subcontractors will not be billing Medicare directly, but instead providing items and services to the main contractor, it seems a gap may exist in the accreditation requirements. Could you please clarify what the accreditation requirements are for subcontractors?

   Answer: The competitive bidding contract requires contract suppliers to maintain compliance with all applicable quality standards and accreditation requirements. Each contract supplier is responsible for fulfilling all of the terms of the contract, even if it uses one or more subcontractors. If a contract supplier breaches its contract due to its subcontractor's failure to perform, the contract supplier will be held liable for the breach. The accreditation organization reviews contracted services that a supplier may be using, thus

ensuring that the contract supplier is in compliance with quality standards, including those services provided by subcontractors. Because contract suppliers are held responsible for ensuring that services meet the quality standards, subcontractors are not specifically required to be accredited. Finally, we note that a supplier may not subcontract with any supplier that has been excluded from the Medicare program, any State health program, or any government executive branch procurement or non-procurement activity.

Rep. Ron Kind

1. How will CMS determine which rural areas will be exempted from the competitive bidding program? Has that determination already taken place? If not, when will it be conducted and what specific information will CMS rely on to make such a determination?

   Answer: The statute provides discretionary authority for exempting low population density areas within urban areas (MSAs) and rural areas (areas outside MSAs) that "are not competitive" unless there is a significant national market through mail order.

   In the final rule, we indicated that we will use this authority if data indicated that an area was not competitive based on one or more of the following indicators:

   a. Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas;
   b. Low number of suppliers of DMEPOS subject to competitive bidding serving the area relative to other similar geographic areas; and
   c. Low number of Medicare beneficiaries receiving fee-for-service benefits in the area relative to other similar geographic areas.

   For Round 1, we used the discretionary authority in section 1847(a)(3) of the Social Security Act (SSA) to exempt a large portion of Eastern Riverside and San Bernardino Counties in the Riverside MSA. We also exempted whole counties in the Dallas, Cincinnati, and Kansas City MSAs. We determined that these areas had low population densities relative to other parts of the MSA and that the allowed charges for DMEPOS items attributed to these areas were low relative to the MSA as a whole indicating that the areas were not competitive when compared to other parts of the MSA. We will use a similar process to determine which areas might be exempted during Round 2.

2. What factors will CMS use to determine when and how it will exercise its authority under Social Security Act (SSA) § 1834(a)(1)(F)(ii) (for DME), SSA § 1824(h)(1)(H)(ii) (for off-the-shelf orthotics), and SSA § 1842(s)(3)(B) (for enteral nutrients, supplies, and equipment), which allow the agency to apply prices from winning bids in other MSAs around the country to rural areas?

   Answer: In a final rule, we stated that we would develop a more detailed plan and conduct subsequent rulemaking prior to using these authorities.

Rep. Sam Johnson

1. In the Final Rule issued April 2, 2007, CMS permits physicians to furnish certain types of competitively bid items without submitting a bid and winning a contract. These items include crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and infusion pumps, but do not include off the shelf orthotics. However, the rule does allow physical and occupational therapists to provide off the shelf orthotics to their patients without participating in competitive bidding because "we have determined that these items would ordinarily be furnished as an integral part of occupational or physical therapy services." Why is there a separate standard for physicians and physical therapists and is there a legitimate concern that this may compromise the ability of physicians to provide medically necessary orthotics to their patients. Why did CMS choose to create a separate standard for physicians and is the agency considering a way to correct this problem?

   Answer: We received comments in the DMEPOS Competitive Bidding Program proposed rule that physicians and treating practitioners should be exempted from the competitive bidding program for certain DMEPOS items. We also received comments that physical therapists and occupational therapists should be exempted from participating in the program because these health care professionals are licensed by State boards.

   In the final rule, we stated that physicians and treating practitioners are exempt from competitive bidding for crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors if furnished to their patients as part of their professional service. A similar exemption applies to physical therapists and occupational with respect to off-the-shelf (OTS) orthotics if furnished to their patients as part of their professional service. This condition applies for OTS orthotics because these items are ordinarily furnished as an integral part of occupational therapy and physical therapy services.

2. The Final Rule requires physicians to become accredited in order to supply any orthotics to their patients in the Medicare program. Due to the cost and paperwork required it is likely that many physicians will likely choose not to become accredited, this will then raise some questions about how beneficiaries will receive medically necessary orthotics. In a separate rule relating to Medicare DMEPOS supplier standards released on January 25, 2008, the agency proposes an across-the-board prohibition on suppliers sharing a practice location with other suppliers—including physicians and other health are practitioners. Physicians at times need to dispense medically necessary DMEPOS items immediately to a Medicare beneficiary—like stabilizing braces, or immobilizing devices. Isn't there a concern that this proposed rule, when considered in conjunction with the new requirements on physicians under competitive bidding, could deny Medicare beneficiaries the ability to receive these medically necessary items when they need them?

   Answer: It is important that Medicare beneficiaries are able to receive the medically necessary items they need. It is equally important to protect our beneficiaries from fraudulent actors. CMS considers both these factors when developing its policies.

The Medicare Modernization Act of 2003 required that CMS establish quality standards for suppliers of DMEPOS items to be applied by recognized independent accreditation organizations and that such supplier shall be required to comply with these standards in order to furnish these items and receive or retain a billing number. CMS does not have the authority to exempt supplier groups and therefore physicians are required to be accredited if they supply a DMEPOS items.

The provision in the Medicare DMEPOS supplier standards rule released on January 28, 2008 is a proposed provision that prohibits suppliers from sharing practice locations with other suppliers. In this proposed rule, we asked for comments on possible exceptions to this rule for physicians and nonphysician practitioners and the circumstances that warrant an exception. Comments were due on March 25, 2008 and we are reviewing the comments received as we finalize the rule.

[Submissions for the Record follow:]

Statement of David Soblick

I am writing on behalf of the Accredited Medical Equipment Providers of America and also on behalf of my organization, Life Quality Home Health Care, Inc and Pharmacy 18, Inc.

I am writing to address some major concerns related to the Medicare DMEPOS Competitive Bidding Program and the standpoint CMS has taken relative to these concerns.

The issue at hand I am referring to is the erroneous disqualification of 63% of qualified bidders due to the poor implementation and mismanagement of the entire program on behalf of CMS' contractor Palmetto GBA, LLC. (CBIC)I would like to shed some light on the manipulation of application rules by the CBIC, Palmetto GBA, LLC and their gross negligence in regards to the program.

Additionally, I would like to bring to your attention CMS's poor and inaccurate analogy purported to congressional staffers concerns about the program during the H.H.S Briefing in Rayburn B-318 on Tuesday, April 22, 2008.

When asked repeatedly why they did not inform applicants of the supposed missing documentation per the original bidding rules, on CMS staffer used the anaolgy of making an application to college.

"Colleges either accept your application or they reject it, they do not call you to let you know that you didn't put something in." They added, "All of the applicants are big boys and they know they are supposed to meet the requirements."

This rationale is not only illogical, it is completely false. I took it one set further just to debunk CMS's analogy some more.

I contacted some admissions offices of various institutions, University of Miami, N.C State, University of Florida, and Southern Methodist University in Texas.

These schools receive on average 30 to 50 times the amount of applications versus the 1,005 bid packages received by CBIC.

They informed me that as with all applicants, "applicant status reports" are routinely mailed out throughout the application period to inform applicants of any change to an applicants file including:

- Change of Information,
- Receipt of New Information (test scores, transcripts, etc.), and
- Missing information (lack of pertinent information necessary for evaluation.)

They further confirmed that when information is missing in an applicants file, they are notified numerous times via email and regular mail, that in order for their application to be properly evaluated by admission staff, they must submit the necessary items *prior to the application deadline*.

To further apply this to CBIC logic and the original Rules for Bidding Instructions, CBIC had every opportunity and ability to properly notify bidders if information was truly missing. Furthermore the bidding deadline was extended twice, giving the CBIC an extra 60 days for evaluation and notification of missing information.

It is analogies like the one referenced above that parallel the poor rationale and illogical blueprint for the entire Medicare DMEPOS Competitive Bidding Program.

I urge the Ways and Means Committee to examine the original biddin g rules that were modified *12 days before the window closed* to excuse contractual responsibility for notifying bidders of missing information in their bid packets. We firmly believe that the 63% of disqualified bidders could have been greatly reduced if not eliminated, had CBIC properly managed the implementation of the Competitive Bidding Program.

Sincerely,

David Soblick
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Statement of Accredited Medical Equipment Providers of America, Letter

Dear Members of the Ways and Means Committee,

I am writing to have a representative from our organization, the Accredited Medical Equipment Providers of America, Inc., speak at the Hearing HL–24. The issue at hand is the Competitive Bidding for Durable Medical Equipment, Orthotics, Prosthetics and Supplies. We have over 100 members that feel that they have been disqualified erroneously or have failed to win a bid due to the poor implementation of the program by the Competitive Bidding Implementation Contractor, Palmetto GBA, LLC.

There have been several problems with this new bidding process; from manipulation of application rules, the rejection of standard REGFLEX policies as required by law and the erroneous disqualification of 63% of the applicants with no ability to appeal. Senators, Congressmen and senior legislative staff have identified these problems as "gross negligence" by the Center for Medicare and Medicare Services (CMS). The results of which will be a limiting of access by patients to much needed care, unqualified companies will be providing incomplete services and major metropolitan areas will be grossly underserved during times of emergency. In addition 17,000 to 21,000 gainfully employed Americans will lose their jobs.

I have included the following attachments and would like to discuss the following developments:

1) A provider from Texas, which has won the Oxygen Category in 9 Metropolitan Statistical Areas, never provided the item before outside of their own area. According to Florida State records, the company is not licensed by Florida's Agency for Healthcare Administration as a Home Medical Equipment Provider. The Bid Winner does not have a License to deliver Oxygen from the State's Accredited Medical Equipment Providers of America 20815 N.E. 16th Avenue—Suite B–32; Miami, FL 33179; 305/654–5957; Fax 1–866–322–2060; www.amepa.us Department of Health either. I am not sure that the company has an Occupational License in the State either.
2) The first line in the Rules For Bid (RFB) states that "All suppliers must—meet any local or state licensure requirements, if any for the item being bid" Clearly this bid winner did not meet the requirements for the bid he won in Miami and Orlando. I also believe that it was not the intent of Congress to allow something like this to happen.
3) According to the Rules For Bid (RFB) companies were required to prove that they could cover the complete geographical area of the MSA prior to bidding. The attachment proves this Bid Winner did not have any subcontract agreements in place before they bid, as they are currently fishing for providers to do their work.
4) This bid winner and other out of state bid winners should clearly not win the bid for oxygen and CPAP. Their bid should be disqualified for not meeting proper licensure requirements. When their bid is disqualified, their bid price should be removed form the Composite Bid and all of the pricing would be affected and other bid losers should take their place.
5) Another attachment is from a bid winner in Miami and Orlando. This winner has changed their policy and as of April 1, 2008 (not July 1, 2008) they are refusing to deliver a commode or other bath safety products unless the order accompanies Oxygen or another rented item. Providers currently compete in the market by providing equipment at a low margin in order to keep the referral source happy. Now the bid winner does not have to compete for business and is refusing to provide these Medicare covered items which are not subject to the bid as they are considered inexpensive. If the Bid winner will not provide these bath safety products then who will provide them?
6) This proves that the program will limit the patient's access to care. If the patient cannot get their prescribed medically necessary equipment from a bid winner they are unlikely able to get the equipment else where as the typical Medicare patient that needs a commode cannot travel to a store to purchase a 24 inch by 24 inch by 24 inch item on their own. It also typically does not fit in a standard compact or mid-size automobile.
7) This patient will most likely not pay for the equipment to be delivered for an additional fee. The patient may likely not get the prescribed equipment at all. It is questionable that this patient may have a home fall due to the lack of proper equipment and that would put extra costs and utilization in Medicare part A programs such as Hospital, rehab and or future Home Health nursing.
8) This also brings into question the ability to discharge the patient from the hospital in a timely manner. As liability issues may not allow for the patient to

be discharged without the proper home medical equipment in place. This will also create increased costs and utilization for Medicare Part A. The program may save money in Medicare Part B but again will increase costs for Medicare Part A. Accredited Medical Equipment Providers of America

Statement of American Council on International Personnel, Letter

Dear Chairman McNulty and Members of the Subcommittee:

Thank you for the opportunity to submit comments for the hearing on Employment Eligibility Verification Systems and the Potential Impacts on SSA's Ability to Serve Retirees, People with Disabilities, and Workers.

American Council on International Personnel (ACIP) is an organization comprised of approximately 200 corporate and institutional members with an interest in the movement of personnel across national borders. Each of our members employs at least 500 employees worldwide, and in total, ACIP members employ millions of United States citizens and foreign nationals in all industries throughout the United States. ACIP sponsors seminars and produces publications aimed at educating human resource and legal professionals on compliance with immigration and employment verification laws, while working with Congress and the Executive Branch to facilitate the movement of international personnel.

The College and University Professional Association for Human Resources (CUPA–HR) provides global leadership to the higher education human resources profession and the higher education community by offering essential knowledge, resources and connections that enhance individual and institutional capacity and competitiveness.

HR Policy Association brings together the chief human resource officers of more than 250 of the largest corporations in the United States. Representing nearly every major industry sector, HR Policy members have a combined market capitalization of more than $7.5 trillion and employ more than 18 million employees world wide

The National Association of Home Builders (NAHB) is a trade association that helps promote the policies that make housing a national priority. NAHB exists to represent the building industry by serving its members and affiliated state and local builders associations.

National Association of Manufacturers (NAM) mission is to advocate on behalf of its members to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing in America's economic and national security for today and in the future.

The Society for Human Resources Management (SHRM) is the world's largest association devoted to human resource management. Representing more than 245,000 individual members, the Society's mission is both to serve human resource management professionals and to advance the profession.

The above-named organizations share the common goal of creating an effective and efficient electronic employment verification system. E–Verify, a voluntary pilot program since 1986, has provided valuable experience on the challenges that will confront any mandatory electronic verification system. For example, this pilot project has given us insight into the wide-variety of worksites and employment situations that must be accommodated, the time commitments and documentation required to resolve discrepancies, and the resources required by employers to train personnel to implement and maintain a compliant system. We believe the New Employee Verification Act (NEVA) (HR 5515) represents the next generation of electronic verification. NEVA builds upon the lessons learned from the pilot project but changes some fundamental aspects to ensure that any mandatory system meets the needs of both the government and employers. The following are the reasons we believe NEVA is a superior solution over simple mandatory expansion of E-verify.

NEVA Builds Upon Existing Programs in Which 90% of Employees are Already Enrolled.

According to the Department of Homeland Security (DHS), only 62,000 of the nation's approximately 7 million employers are enrolled in E–Verify. DHS notes that 2,000 employers are enrolling every week. These statistics belie the grave challenges in enrolling all U.S. employers. With less than 1% of employers currently enrolled, even at a rate of 5,000 employers per week, it would take over *25 years* to enroll all current U.S. employers! The problem of enrolling employers is illustrated in Ari-

zona, which mandated E-verify use by all employers as of January 1, 2008. Despite the fact that businesses can lose their license for failing to use E-verify, fewer than 15% of employers have enrolled.

NEVA avoids the tremendous burden of enrolling virtually all employers in a new system by building upon an existing system that has proven its effectiveness—the National Directory of New Hires. Over 90% of employers currently report new hires to this system which is used to check for child support enforcement. While modifying the National Directory of New Hires for this new purpose would admittedly require resources, the burden would be much less than expanding the current E–Verify pilot program. Resources could be devoted to improving the databases instead of educating employers on enrollment. Employers have been participating in their states "new hire" database since 1986 and are already familiar with the processes and procedures for reporting necessary information. NEVA would utilize information in the new hire database to determine if a new employee's information is consistent with information maintained by SSA or by DHS.

NEVA Provides the Resources to Fix the Database Problems that Hamper E-Verify

Our associations represent thousands of employers who desire a reliable system for determining who is authorized to work in the United States. Mistakes and delays in this process could prove to be costly for a number of employers and employees who are caught in the system. The current system, if mandatory, could prove to be unreliable in terms of providing employers with an effective and efficient electronic employment verification system.

In 2006, SSA's Inspector General issued a report estimating that there are discrepancies in approximately 17.8million (4.1 percent) of the 435million social security records. These errors include incorrect social security numbers, names, dates of birth and citizenship status. A recent report compiled by the CATO Institute, and using the estimates from SSA's Inspector General, determined that a mandatory electronic employment verification system would result in 11,000 workers per day receiving a tentative non-confirmation throughout a given year (based on an average of 55 million hew hires per year).

Furthermore, according to a Government Accountability Office (GAO) report released last year, "resolving some DHS non-confirmations can take several days, or in a few cases even weeks." As more employers enroll, this timeframe is likely to get longer. As GAO noted, the expansion of E–Verify will "affect the capacity of the system because of the increased number of employer queries."

NEVA takes several steps to resolve these database errors so that employers and employees will have fewer tentative non-confirmations to resolve. First, NEVA provides for advanced appropriated funds and staffing to clean up the databases. This will benefit not only work authorization, but also the other government programs that rely on these databases for information. Second, NEVA requires SSA and DHS to certify the accuracy of the system in advance of full implementation and annually thereafter. Finally, NEVA requires the GAO to evaluate the accuracy, efficiency and impact of the employment verification system. These checks in the system will ensure that employers are not hamstrung by a system that does not enable them to hire U.S. citizens and other legal workers with ease and certainty.

NEVA Is Truly "Electronic"

There is a great deal of misunderstanding about our current "electronic" pilot program which is really not an all "electronic" system. While E–Verify requires employers to submit an inquiry via the internet to confirm work authorization, an employer can submit this only after it has completed the Form I–9 and examined one or more of 24 paper-based documents to establish identity and work authorization. Employers must retain two sets of records—the electronic one and the Form I–9 (which can be maintained in paper, on microfiche or electronically). Some proposals would expand this dual-recordkeeping by requiring employers to keep photocopies of the documents examined and to record the electronic approval or denial number on the Form I–9. All of these steps cost employers time and money and open the possibility for recordkeeping mistakes.

NEVA brings recordkeeping into the twenty-first century by creating a truly "electronic" verification system that eliminates the Form I–9 (known as the Electronic Employment Verifications System (EEVS). In addition, NEVA provides flexibility and easy accessibility for all employers by allowing electronic inquiries over the internet and telephone and builds upon a database that is already used by many employers.

NEVA Protects Against Identity Theft

One of the acknowledged weaknesses of E–Verify is that it cannot detect stolen identities. Thus, if an undocumented worker presents legitimate but stolen or forged documents that contain the identity of a U.S. citizen, the worker will appear to be work-authorized, duping the employer into hiring and training someone who may ultimately be deported.

NEVA addresses this problem by allowing employers to elect to participate in a program that makes identity theft extremely difficult. The Secure Electronic Employment Verification System (SEEVS) enables employers to send newly hired employees to government certified private companies that will authenticate their identities through the use of publicly available databases. An employee's identity is temporarily "locked" with a biometric tool until work authorization is verified by the government. Many employers are willing to pay for this additional assurance, particularly where it builds upon other background screening they are already doing.

Individuals could also benefit from this more secure system. Under EEVS or SEEVS, employees could choose to "lock" their identity and their social security number, thus making it very difficult for anyone to steal their information.

SEEVS is a more advanced system than the photo screening tool currently piloted by DHS. It does not require employers to make subjective determinations by visually comparing a scanned photo to a paper document. Furthermore, it does not require integration with state driver's license or Federal passport databases. The photo tool is currently limited to verifying the authenticity of Lawful Permanent Residents or individuals with Employment Authorization Documents that contain a photo which comprise a very small percentage of the workforce. Efforts to expand this tool to driver's licenses and passports will take years.

NEVA Preempts the Patchwork of State Employment Verification Laws

Frustrated with Congressional inaction on immigration reform, a growing number of states are mandating the use of E-verify for employers or contractors, and the list continues to grow. The expanding patchwork of state employment verification laws is causing many problems for human resource managers and employers struggling to maintain consistent and compliant practices across the country. Federal relief is needed.

Many states are exploiting the current INA provisions under 8 USCA 1324 (a)(h)(2) on employment practices. While the language preempts "any State or local law imposing civil or criminal sanctions (other than through licensing and similar laws) upon those who employ, or recruit or refer for a fee for employment, unauthorized aliens," states like Arizona have been using the "licensing exception" language to mandate the use of the E–Verify system—a system that is not ready for large-scale expansion. NEVA clarifies that immigration is solely the purview of the Federal Government by establishing a clearer preemption standard that protects both employers and employees from a patchwork of state laws.

Our organizations strongly support a uniform national policy towards employment verification. The employers we represent want an efficient, effective, and powerful electronic tool to prevent unauthorized employment. We need strong reform that is realistic and workable. That is why we, the listed associations, support HR 5515, the New Employee Verification Act (NEVA).

Thank you for your attention and consideration of our association's views.

Statement of American Hospital Association (AHA)

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide a statement for the record on Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program.

In an effort to reduce Medicare's costs for DMEPOS, the *Medicare Modernization Act of 2003* directed the Centers for Medicare & Medicaid Services (CMS) to establish a competitive bidding process for these products and services. The AHA supports potential congressional efforts to allow hospitals to participate in the Medicare DMEPOS program but to be excluded from the bidding process. This would allow hospitals to continue to provide equipment and supplies directly to their patients during a hospital stay and upon discharge to their homes and communities.

While the AHA supports the broad goal of Medicare's competitive bidding program, we remain concerned that the implementation of certain CMS regulations will

restrict the ability of many hospitals to meet their patients' DME needs in a clinically comprehensive and timely manner. To avoid this problem, hospitals wish to continue participating in the DMEPOS program by accepting the price set through the competitive bidding process, without being required to submit a bid. This approach would treat hospitals in the same manner in which physicians are treated under the DMEPOS competitive bidding program. It recognizes that, unlike DMEPOS vendors, both physicians and hospitals are health care providers primarily focused on treating patients.

This would allow hospitals to continue serving their patients without interfering with the DMEPOS prices set through the competitive bidding process and, therefore, would avoid adding costs to the Medicare program.

This proposal would benefit patients who need DMEPOS, as well as patient education and support on the proper use of the DMEPOS. This is especially critical for medically complex patients who need more advanced DMEPOS to be able to return home safely. Large DME vendors place less emphasis on the training, education and ongoing technical support needed for this type of DMEPOS, instead preferring to focus on achieving the most cost-efficient methods of delivering high-volume DMEPOS. Without being able to rely on the hospital for comprehensive DMEPOS services, patients who need more customized care and specialized DMEPOS might not be discharged as directed by the treating physician in a timely fashion. In addition, the lack of comprehensive patient and caretaker education and technical support could result in the inappropriate and unsafe use of DMEPOS.

To ensure that beneficiaries have timely access to DMEPOS and comprehensive service, we urge you to support legislation to allow hospitals to continue participating in the Medicare DMEPOS program without submitting a bid, thereby benefiting Medicare patients without adding cost to the program.

We thank you again for the opportunity to submit a statement for the record on Medicare DMEPOS Competitive Bidding Program and look forward to collaborating further on this important issue.

Statement of American College of Physicians

Mr. Chairman and Members of the Committee:

We appreciate the opportunity to submit this statement for the record and will limit our joint comments to addressing two requirements established by the Medicare Modernization Act (MMA) in the *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)* that are problematic for the members of each of our organizations.

First let us note that our organizations appreciate that the Centers for Medicare & Medicaid Services (CMS) exempted physicians and "treating practitioners" from having to participate in the competitive bidding program when they provide certain specified DMEPOS to their own patients as part of their professional services, and when the items are billed using a billing number assigned to these practitioners.

We are concerned, however, with two requirements that could have an adverse impact on Medicare patients. First, we believe that requiring physicians and licensed health care professionals (hereafter referred to as health care professionals) to be accredited in order to continue supplying DMEPOS when treating patients is both financially and administratively burdensome.

Second, we believe that CMS is inconsistent in its application of competitive bidding requirements for health care professionals for such items as off-the-shelf orthotics (OTS), crutches, canes, walkers, eyeglasses following cataract surgery, and folding manual wheelchairs when provided as part of their professional service.

The clinical judgment and expertise of health care professionals is critical for selecting, sizing, and fitting DMEPOS, as well as educating patients on their use. Many patients require immediate access to such items for immobilization, injury support, facilitation of safe mobility, or post-surgical recovery. It is unsafe and clinically inappropriate to delay or deny a patient's access to items such as orthotics, eyeglasses, or ambulatory support devices, or to send a patient out of a practitioner's office without the necessary DMEPOS.

Accreditation

In the MMA, it appears there is no recognition that health care professionals who supply DMEPOS integral to patient care are wholly dissimilar from suppliers who furnish DMEPOS products to the public as their primary source of income. There is also a lack of recognition that health care professionals not only prescribe appro-

priate items of DMEPOS, but must frequently and expertly dispense and educate patients on their use at point of treatment.

As a result, CMS has made relatively few accommodations for the more than 38,000 physicians who currently have DMEPOS supplier numbers, as required by CMS, in promulgating supplier accreditation standards. Health care professionals are not in the business of providing DMEPOS to the public as a business, and we believe it is unwarranted and unreasonable to require them to be accredited in order to provide the patient services for which they have been educated, trained, and licensed.

Furthermore, as of March 1, 2008 Medicare required health care professionals who are either new to the program or are existing suppliers looking to open a new practice location to become accredited prior to obtaining a national supplier clearinghouse (NSC) number. This requirement is unduly burdensome and unjust to health care professionals who are just beginning to practice or are looking to expand the quality of the integral services they provide to their patients. The deadline for existing suppliers not changing their practice is September 30, 2009.

Health care professionals who provide DMEPOS products to their Medicare patients are licensed by the state in which they practice and are thus subject to a wide range of state regulatory and other requirements. DMEPOS suppliers who are *not* health care professionals obviously do not and cannot satisfy these requirements.

CMS' claims data indicates that DMEPOS products furnished by health care professionals make up a small portion of the Medicare-covered DMEPOS charges—slightly more than 3 percent according to 2004 claims data. It is unclear, therefore, what, if any, program improvement or cost savings would be realized by imposing these requirements on health care professionals who only dispense DMEPOS when providing patient treatment.

Consider, for example, that some health care professionals who supply DMEPOS receive an average total reimbursement (gross) of $7,000 per year from Medicare for these products. Accreditation costs approximately $3,000 per office for up to a three-year period. The accreditation process is time-consuming, expensive, and heavy on paperwork—precisely the type of barrier that large companies are equipped to surmount, but which pose special difficulties for small health professional businesses that do not or cannot afford to hire additional full-time regulatory compliance staff.

A supplier manual from one of the CMS-sanctioned accrediting organizations for physicians is 128 pages, and represents the administrative red tape for meeting the CMS requirements. It is not difficult, therefore, to understand why health care professionals find it impractical to seek accreditation just to continue dispensing relatively small quantities of DMEPOS in their offices. It would essentially be impossible to recoup these costs given the amount Medicare pays for the small quantities of DMEPOS products furnished to their patients.

Additionally, many of the DMEPOS supplier quality standards and proposed enrollment safeguards do not make sense in the context of a health care professional's practice. For example, it would not be practical nor would it appear to serve any useful purpose to require all the health care professionals in a large professional building to each have a sign visible at the main entrance of the building with their business hours (as recently proposed).

Similarly, health care professionals are concerned that the proposed enrollment safeguard precluding a DMEPOS supplier from sharing a practice location with another Medicare supplier, "including a physician/physician group or another DMEPOS supplier," would inappropriately prevent a health care professional from providing both DMEPOS products and professional services to patients in the same practice location.

Ultimately, requiring additional, unnecessary, and redundant accreditation requirements of health care professionals may keep them from dispensing necessary DMEPOS items at point of treatment. Unfortunately, this could inconvenience or endanger Medicare beneficiaries, and compromise the health care professional's objective of providing the most appropriate quality care and of doing patients no harm.

The only other available alternative would be to refer the beneficiary to a DMEPOS retail supplier, which may be unsafe for the beneficiary, prolong access to appropriate treatment, or, even worse, prevent the beneficiary from receiving the proper item because there is no DMEPOS retailer in close proximity. Sadly, either outcome would be a gross disservice to Medicare beneficiaries and place health care professionals at risk for not immediately providing necessary care.

Inconsistent Exemptions from the Competitive Bidding Process

A second immediate concern is that, while we appreciate that CMS exempted physicians and "treating practitioners" from having to participate in the competitive bidding program when they provide certain specified DMEPOS to their own patients

as part of their professional services, there seems to be an inconsistency in how the determinations were made for who would be exempt for what products.

For instance, CMS did not exempt physicians and what they term "treating practitioners" who dispense off-the-shelf (OTS) orthotics, but did exempt them from bidding for other DME (crutches, canes, walkers, and folding manual wheelchairs). Alternatively, physical therapists (PTs) and occupational therapists (OTs) are exempt for OTS orthotics, but not for crutches, canes, walkers, and folding manual wheelchairs.

Failure to exempt physicians and "treating practitioners" from having to competitively bid to furnish OTS orthotics to their patients, and failure to exempt PTs and OTs from the competitive bidding process for select DME, including, crutches, canes, walkers, and folding manual wheelchairs, could cause significant access and patient safety issues.

Providing such DMEPOS items is an integral part of patient care for many health care professionals. Failure to provide these exemptions to all health care professional groups is inconsistent and raises significant access and patient safety concerns.

Given the inconsistency of the DMEPOS final rule, and the threat to patient care posed by health care professionals being effectively prohibited from providing certain DMEPOS, the undersigned organizations have strongly urged CMS to permit health care professionals to continue supplying the aforementioned DMEPOS items to their patients without participating in the competitive bidding or accreditation processes.

We look forward to working with the House Ways and Means Committee and CMS to find a way to address these accreditation concerns and to avoid access issues for patients who rely on health care professionals to provide DMEPOS as part of their care.

Statement of Andrea Logan, Letter

Dear Mr. Chairman

I am writing to you today regarding the upcoming DMEPOS Competitive Bidding hearing on May 6th, 2008. I am so very pleased that you and your colleagues are taking this issue so seriously.

I have owned and operated a nursing home medical supply company in Michigan, since 1995. We currently supply over 500 beneficiaries with enteral nutrition therapy in skilled nursing centers throughout Michigan. I employ 25 exceptional people.

The upcoming competitive bidding program will impact my business severely. Based on the "Single Payment Amount" that is offered in the first round of bidding we will see a dramatic decrease in profit and ability to serve the frail elderly here in our state. We are making plans to educate our customers on the upcoming second round that we will be part of and determining if we will even be interested in moving forward with this service.

Our company did submit bid in the first round and were not offered a contract. The reason given was that our bid was too high. I based my bid on true "cost the serve" and considered the fact that beneficiaries should be able to receive whatever is clinically necessary and therefore there are times when we need to supply a product that does not cover our cost or at very little profit, once all the paperwork, delivery, set up and clinical in-servicing has taken place.

Many suppliers underbid in the hopes of expanding their business through "joint ventures or sub-contracted relationships". Those relationships did NOT have to be accredited or meet ANY CMS requirements I do know this to be true as I too used a "sub-contracted relationship" to serve an area that we are currently not in. Low bidders also expect to receive additional discounts with the two manufactures of enteral nutrition. (Nestle/Abbot Nutrition).

Unfortunately the manufactures (Nestle/Abbot Nutrition) are faced with the same issues that all businesses are facing: rising fuel, raw material costs and health care. The bottom line is that beneficiaries will suffer. The types of nutrition they may require will be ignored do to cost, additionally there was no verification process that assured a "sub-contracted relationships" could actually perform the necessary services.

We currently make a small profit on a few products today based on the current "fee" schedule; however we make it up on other product categories so it has not been an issue for us to provide what is clinically best for the beneficiary. For bidding pur-

poses going forward that will be a greater consideration on what products are selected for bidding in a particular category.

Here is an example of what I am referring to:

	Billing Units/ Month	Cost per Billing Unit	Current Fee Screen	Monthly Profit/ Loss
Resident on 1800 calories per day Isosource 1.5 or Nutren 1.5 HCPC Code B4152	558	$.45	$.58	$ 72.54

	Billing Units/ Month	Cost per Billing Unit	Single Payment Amount	Net Profit Loss w/SPA
Resident on 1800 calories per day Isosource 1.5 or Nutren 1.5 HCPC Code B4152	558	$.45	$.43	$(11.16)

The costs of these products are effective today 4/30/08. These 2 products are high volume product codes for Nestle. The manufacture of these products have told us that pricing beginning 6/1/08 will increase approximately 8–10%, adding further to the loss on patients requiring these nutritional products.

Lastly I would like to draw your attention to the latest practice by winning suppliers in round one. I received a letter today from a winning supplier that is offering suppliers who were not offered a bid the ability to "purchase these patients from your organization". In my opinion this is opening the door to beneficiary neglect at the highest level, it will also further add to confusion for the elderly in particular.

As a supplier in good standing I certainly agree with the accreditation process, and need to lower the burden on the increasing demands of Medicare and Medicaid. I simply ask why could CMS not have lowered the current fee schedule? If in fact it was only to lower costs, then this would have been a very simple task and we as suppliers would have shared the burden. The fee schedule cut could also be immediate, unlike the Competitive Bidding program which I am sure has cost more to this point than any savings that may or may not be realized by CMS.

I strongly urge you and your committee to not only delay the next round but seriously consider the future of the competitive bidding program altogether.

Thank You,

Andrea Logan
President—All Med Medical Supply LLC
All Care Billing LLC

Statement of Angelene Adler, Letter

Dear Members of the Subcommittee on Heath,

The intent of this letter is to encourage your attention to the mis-administration of the Centers for Medicare and Medicaid (CMS) Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. I am writing this letter as a deeply concerned citizen, constituent, and businessperson. Established in 1970, Care Medical Equipment, Inc. is an independent, family-owned company that has grown to include ten branch locations throughout both Oregon and Washington states. Care Medical specializes in home medical equipment services, rehabilitation equipment services including custom seating and positioning, bariatric equipment and respiratory equipment services including home medical ox-

ygen, ventilators, and sleep apnea products and has been serving the needs of the Pacific Northwest for nearly 38 years.

We continue to notice the inconsistencies in CMS' administration of the Medicare Modernization Act of 2003 (MMA), and are especially concerned with its recent implementation of the Competitive Bidding Program. This policy has the potential to adversely affect well over 42 Million U.S. citizens who are current Medicare recipients (as of the most recent 2005 Centers for Medicare and Medicaid Services (CMS) Statistics Systems). CMS Secretary Leavitt and Administrator Weems' interpretation of this program disregards the individuality of our patients in need of complex rehabilitation equipment that takes a tremendous amount of customer attention to assure proper fit and function. Without individualized custom equipment, patients often develop alternative complications that ultimately cost the Medicare system considerably more.

Several studies have demonstrated that competitive bidding will be a tragedy for the healthcare industry and Medicare beneficiaries alike. Furthermore, savings brought on by the CMS program will be substantially offset by increased administrative costs associated with implementation and oversight of the Competitive Bidding Program ensuring lowered standards of patient care. The first study I am referring to was a peer-reviewed study conducted jointly through Kennesaw State and Drexel University, and published in the Southern Economic Journal in January of 2008. The primary focus of this study was to examine the Polk County, Florida and San Antonio, Texas CMS Competitive Bidding demonstration projects. The main premise of the report found that the process was: "inefficient, leads to price increases and may cause decreases in the quality of services."

The second report I would like to refer to is the recent Robert Morris University. That found the CMS bidding program is optimally designed to reduce the number of DME providers (business' such as mine), thus concentrating the home care market into a state of monopolies. This study points out that concentrated markets usually result in higher, not lower, prices of services, and consistently lowered standards of quality. This is not an acceptable practice for America's healthcare system. This study also concluded that loosing DME suppliers would likely be forced to terminate their businesses since approximately 40% of their business is Medicare related. The outlook of both studies casts heavy doubt as to the effectiveness of the current CMS Competitive Bidding Program.

More poignantly, CMS recently received 6,300 bids from 1,005 providers whoparticipatedin the first round of competitive bidding. Out of those initial 1,005 bidding providers, 630 (63%) were disqualified due to "incomplete" submissions or responses to the CMS Request for Proposal (RFP). Unfortunately, there seems to be significant problems with companies being inappropriately disqualified from consideration for the bidding program without sufficient evidence for dismissal. Those bidding providers have no recourse for reconsideration since bids will be awarded prior to resolution of provider grievances. This effectively renders their bids null, void, and victim to a CMS policy that adheres to meaningless process without recourse.

The American Association of Homecare (AAHC) has begun to document DME companies that were disqualified from the CMS Competitive Bidding Program for: 1) not providing requested financial information—when the companies have hard copies demonstrating they did indeed provide the information, 2) not responding to requests for additional information—when the companies have Fed Ex receipts and fax confirmations that the information was indeed sent, 3) failing to take adequately into account bidder's capacity to provide services to Medicare beneficiaries, and 4) awarding bids to companies who do not have established business locations in the prospective bidding area (as outlined in the CMS standards of participation).

We believe that the large number of disqualifications raises serious questions regarding the adequacy, and competency of the CMS Competitive Bidding Program. Continuously, our industry has requested additional information regarding this program, and have been routinely denied adequate accommodation. What concerns us even more is the non-disclosure policy CMS has taken making it impossible to ensure transparent government oversight of such essential services. We feel it imperative that prior to implementing round one of the CMS program that a minimum 6-month postponement for essential third-party evaluation be commissioned before patient care is potentially compromised.

The home Durable Medical Equipment (DME) industry continues to be most cost-effective resource for the Medicare recipient. Unfortunately, as Medicare allowables continue to dwindle, our direct costs of service continue to exponentially increase. Nationwide, providers are evaluating whether they can simply survive at the current reduced Medicare allowables, let alone at the steep reductions that would make many essential items unprofitable. Essentially, the only willing bidders will be those "low ball" bidders incapable of rendering services once awarded contracts or non-

scrupulous and unqualified parties interested in locking out competition for the sake of monopolization, which would lead to the further detriment of both healthcare providers and patients alike. This circumvents the competitive marketplace, and ensures making our healthcare market ripe for future fraud, collusion, and abuses in patient care.

CMS needs to realize that competitive bidding eliminates incentives for suppliers whether the supplier "wins" the bid or not for any product category. Presently, beneficiaries have numerous choices regarding equipment selection because of our free-market enterprise system that allows patients to choose both their provider and type of equipment. Competitive bidding will force suppliers into providing lesser quality products and supplies in order to maintain sound business practices. Suppliers will simply be unable to provide equipment in as efficient a manner under competitive bidding regulations. Services to patients that include delivery, setup, maintenance, education, quality control, product availability, and patient access will decline as a direct result of this incentive elimination.

With the implementation of Round 1 we have seen winning providers who currently have no physical location, are not accredited, and do not have certified & licensed staff. One of the major national competitors is recognized for these types of business practices, and in 2005 was fined $4 Million for its fraudulent practices in dealing with Medicare (available: http://www.hmetoday.com/news/2007–05–14—01.asp). We find it interesting that CMS continues to support policies detrimental to patient care, and yet supports fraudulent abuse in the marketplace.

The CMS Competitive Bid Program is bid by product categories, such as Complex Rehabilitative Power Wheelchairs, Continuous Positive Airway Pressure Devices (CPAP), Hospital Beds, and Oxygen Supplies/Equipment. Providers of services who were able to provide prescribed equipment may not be able to do so in all product categories if they are not awarded the bid for that particular product category. In simple real-life terms, this means that a patient, caregiver, physician, discharge planner, case manager, or physical therapist could very likely be forced to call numerous providers to request each individual item such as a wheelchair, walker, and oxygen concentrator for patient discharges. Under the CMS Competitive Bidding Program these stakeholders may have to contact multiple providers just to meet the specific needs of the patient. Why is this bad? Because, DME providers currently compete for the business of both our customers and referral sources. If competition is alleviated there is no incentive to meet hospital or skilled nursing discharge timelines to return patients to the home setting. With such reductions in competitive quality control measures, increased hospitalization stays are inevitable, which results in increases to Medicare expenditures on the hospital side.

Suppliers are being asked to make a bid that encompasses analyzing so many variables that are out of their control such as shipping costs, gas costs, and manufacturer price increases as well as increases in employee benefits such as health insurance. We propose that all suppliers be allowed to bid, regardless of the size of the organization. If suppliers agree to quality and financial standards set by CMS and they accept established payment amounts, suppliers should be allowed to service all Medicare beneficiaries in the areas they serve. CMS would be better off adhering to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act of 2000. The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment.

The CMS Competitive Bidding system is only going to enhance the strength of the national DMEPOS providers who are already decreasing the volume of staff involved in customer service and education to meet the demands. We at Care Medical share the general consensus of the DME industry in that decreasing the number of DMEPOS suppliers in this manner will not allow for increased competition, but will rather encourage lowered quality product and reducing the level of customer service being provided to beneficiaries. Decreasing competition in the DME industry can only be detrimental to patient care. DME providers cannot increase prices charged to Medicare (they are set by the CMS governed fee schedule), and various state Medicaid programs.

Providers of services earn the business by providing high quality products, services, and care. Simply stated, eliminating competition eliminates the incentives that our free-market economy is based on. We also find it abhorrent that apparently no thought or consideration has been given to the emotional or economic impacts of the resulting displaced workers. This is a much larger issue than realized at first glance. These employees and their families are dependent upon their jobs for basic food, shelter, and healthcare.

Furthermore, Competitive Bidding is not a necessary strategy in reducing Medicare expenditures, nor is it an appropriate response to dealing with recent fraudu-

lent practices in the industry. Allowables can be reduced, quality standards can be enacted/enforced, and accreditation requirements should be strictly upheld. These are the direct responsibilities that have been constantly neglected under Secretary Leavitt and Administrator Kerry Weems. Incidents of fraud and overutilization have occurred specifically due to lack of oversight and enforcement of CMS. Competitive Bidding will not resolve any of the underlying issues that support fraudulent practices such as overutilization. Perhaps the more pertinent question ought to be: Why did CMS supply so many fraudulent providers with supplier authorization numbers without inspections/enforcement of its own regulations?

The Medicare Access to Complex Rehabilitation and Assistive Technology Act of 2008 (HR2231/S2931) would effectively exempt complex rehabilitation equipment from the CMS Competitive Bidding Program. Complex rehabilitation equipment is custom-configured items and requires extensive customization for each patient due to serious disease and disability. Often, these patients cannot afford the out-of-pocket expenses associated with complex rehab equipment necessary to continue being productive members of society. We request your offices to contact Senator Baucus (D–MT) and urge for the addition of this legislation to the upcoming Medicare package.

It is of our opinion that CMS Competitive Bidding Program is a lose-lose public policy for healthcare, citizens, and business' alike. Our company requests delaying Round 1 of the CMS DMEPOS Competitive Bidding Program for a minimum 6 months period to obtain a third-party evaluation of the program. This CMS program has been fraught with procedural and operational flaws that continue to threaten the integrity of the entire homecare industry, consequently affecting small businesses such as myself, and ultimately the access of those Medicare beneficiaries whom we serve.

Respectfully yours,

Angelene Adler, Vice President
Care Medical & Rehabilitation Equipment
1877 NE 7th Ave
Portland, OR 97212
(800) 952–9566

Statement of Annie Nation

To: Congressman Sam Johnson,

I am writing to express a concern regarding the Competitive Bidding Program implemented by the Centers for Medicare and Medicaid Services. As a supplier of Durable Medical Equipment this program will force us to close our doors and the beneficiaries will lose.

On July 10, 2007 I mailed all the required documents to the CBIC. They received the package tracking number EB57 3048 087US on July 11, 2007 at 12:43 pm in Augusta GA. The items were signed b L BENEFIELD. The contracts were issued to suppliers on Friday 21, 2008 via Federal Express. I did not receive my letter because they mailed it to my home rather than my office which is on their files and every agency that is associated with this program. On July 21, 2008 I spoke to Jean Catalano (803) 763–8194 the Program Manager for Palmetto GBA who is overseeing the CBIC Program. Ms. Catalano statement to me was "You better pray to God that the error was on our part rather than yours". After 48 hours on Tuesday March 25, 2008 at 8:28 am Trish, called me and said they are still looking for the paperwork and someone will call back in 48 hours. On Friday March 28th 2008 Lisa Edwards from Palmetto called and stated it will be 30 days before we find your paperwork, but less than 30 days. How is it possible for all the providers to have the same or similar documents missing?

One day the CBIC told Congressman Johnson's office they found my paper work and that same evening I received an email saying they did not. As of May 1, 2008 the CBIC and CMS has told me that the documentation was never found and as of July 1, 2008 I will no longer be able to provide service for our patients. CMS has not provided any information nor have they found a resolution for the disqualified suppliers. Their answer is we will notify you in a letter what our findings are. This is a communistic way of doing business. CMS chooses who they want to do business with and eliminate the ones they don't. What happened to free enterprise? What happened to protecting the small businesses the very back bone of this country. What CMS and CBIC have said and what they did are very different. What they

have told our elected officials are all lies. That is if they decide to communicate with them. They have entirely too much power. Not all suppliers are fraudulent.

Sincerely,

Annie Nation,
President

Statement of Capital Medical and Surgical, Inc.

To: House Ways and Means Health Subcommittee
From: Capital Medical and Surgical, Inc.
Re: CMS DMEPOS Competitive Bidding Program

The current CMS DMEPOS Competitive Bidding Program has many flaws, and is not good for the Medicare patients, or the DME/HME industry.

Many providers will be prevented from servicing the senior population under this program. This will result in substandard patient care and service. By reducing the number of DME providers able to serve this population, many of these needed seniors will not be provided the level and quality of service that they require.

Most of the DME providers are small business that are focused on providing the needed service for this senior population. With the competitive bidding program in its current form, many of these small providers will be forced to close their business.

If the goal of CMS is to lower costs, there are better ways to do it than limit the number of providers for the growing senior population.

Statement of Cara C. Bachenheimer

Introduction

Invacare Corporation (NYSE: IVC) is the global leader in the research, development, manufacture, and distribution of the broadest product offering of innovative home medical equipment (HME) that promotes recovery and active lifestyles for seniors and people with disabilities. We sell a broad array of products to approximately 10,000 HME providers in the United States, including manual and power wheelchairs, other mobility aides such as canes and crutches; respiratory products such as oxygen concentrators, portable oxygen systems, and new oxygen technologies; nebulizer compressors and respiratory disposables; sleep therapy products; home care beds; low air loss therapy products; bath safety products; and patient transport equipment. In turn, our HME provider customers interface directly with Medicare beneficiaries in their homes by furnishing and servicing these items. The majority of this equipment falls under the definition of "durable medical equipment" as defined under Part B of the Medicare Program.

Background

Section 302(b)(1) of the Medicare Modernization Act of 2003 (MMA) requires, the Centers for Medicare and Medicaid Services (CMS) to implement a "competitive acquisition" program for certain items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). In 2007, the bid submission process began in ten of the largest metropolitan statistical areas (MSAs), and bid rates will be implemented on July 1, 2008. The first ten bid areas are: Charlotte, Cincinnati, Cleveland, Dallas/Ft. Worth, Kansas City, Miami/Ft. Lauderdale; Palm Beach, Orlando, Pittsburgh, Riverside/San Bernadino, and San Juan. The "competitive acquisition" program will expand to 70 additional MSAs in 2009, and beginning January 1, 2009, CMS has the authority to apply bid rates in non-bid areas. The MMA allows the Secretary to contract with only as many providers as the Secretary deems necessary to meet the demand of an area. Any provider not awarded a contract will be prohibited from participating in Medicare for bid items and services for up to three years.

On March 21, 2008, CMS and its contractor, CBIC,[1] notified bidders of whether they would be offered a contract to provide items the suppliers bid on in each of the initial ten metropolitan areas. The CBIC had six months to review the bids, and requested a 10-day turnaround for suppliers to respond with a "Yes" or "No" an-

[1] The Centers for Medicare and Medicaid Services (CMS) contractor for administering the bid program is the CBIC, or Competitive Bidding Implementation Contractor. Palmetto GBA, based in Columbia, SC is the CBIC.

swer, and has stated that it needs four weeks thereafter to finalize the list of "winning" bidders. We expect CMS to announce today the list of winning bidders in each of the ten markets and the program is scheduled to be effective July 1, 2008. This means that patients will have no more than seven weeks to find a winning supplier if theirs did not "win" and transition their products and services to the other supplier. Winning suppliers will take a 26% payment cut and will have a short period of time to ramp up product inventories (assuming they are credit worthy), hire and train new staff, purchase trucks and in many cases will have to establish a new business location in the MSA.

The bid process forces HME providers to bid only lowest prices, despite current rapid inflation and dramatically increasing costs such as fuel. Winners of the bid do not really "win" as do military contractors who enjoy a guarantee of certain volume. Instead winners merely get the right to continue competing in the marketplace. Further, bidders were not obligated to sell at the prices they bid (unlike Medicare Part D contractors); providing skewed incentives that fundamentally distort the bid process so that bid prices have no relation to market prices. CMS allowed companies to bid who had no physical location in or near the bid area. For beneficiaries with respiratory and/or high end rehab needs, it is not possible to appropriately serve beneficiaries long distance.

CMS is planning to implement Round Two of the program in an additional 70 areas, and will begin the bid process this summer. Round Two will add 18 million Medicare beneficiaries to the program.

Manufacturer Impacts

On July 1, 2008, when the bid program goes live for the first ten MSAs, Invacare believes there may be significant problems in the credit markets for the industry. Many providers who lost bids have become bankruptcy risks for all manufacturers, if those providers rely heavily on Medicare as a payor. It will also be difficult for manufacturers to provide winning firms with the credit they are seeking given the lack of guaranteed volumes, the significant payment cuts, and in some cases, the size and financial stability of the company. These credit exposures will become larger and more difficult to manage as the bid program is rolled out nationwide. Further complicating the credit problem is the fact that CMS offered contracts to many bidders who have no presence in and have no history or experience in providing the product and services in the particular bid area. The impact of credit issues at the provider level may well ripple through to manufacturers particularly as the process continues into 2009.

Consumer Impacts

Beneficiary Access to New Technology—Home respiratory technology has evolved substantially over the last ten years. New home oxygen technology is essential to meet the clinical needs of all beneficiaries. New oxygen technology is more complex, difficult and expensive to produce and is not a commodity class of goods. Physicians and patients prefer the innovative, new oxygen technologies due to the impact clinical outcomes and quality of life. Importantly, new oxygen technologies will prove to be more cost effective for the Medicare Program and the beneficiary. The President's intention to protect new oxygen technology was ignored in the bidding process.

Despite the many advantages of newer oxygen technologies, the way that CMS has structured the bidding program will stymie consumer access to these technologies due to the antiquated code system that requires providers to use the same code to bill for traditional and new oxygen technologies. CMS could easily fix this problem by creating a separate billing code for the stationary component of new technology, as it has for the portable component of new technology. Beneficiary access to new oxygen technology is further exacerbated by the Deficit Reduction Act's requirement that the beneficiary assume ownership of all oxygen equipment at 36 months. Under the bid program, CMS' final rule requires contract suppliers to serve all beneficiaries; many beneficiaries will presumably transfer from their supplier who lost to a contract supplier. Contract suppliers will therefore begin to serve beneficiaries who have been on oxygen for some months; without the assurance of 36 months of payment. In fact, contract suppliers have no idea before the program starts how many home oxygen beneficiaries it will be serving, nor do they know at what month of medical need all these beneficiaries will be in. In this situation, the contract supplier will be forced to provide the least expensive oxygen system, which is certain to be the oldest equipment. As a result, new technology which physicians and patients prefer, and which requires significantly higher up front investment, is likely not to be provided to beneficiaries in the bid areas.

Beneficiary Access to High End Rehab Services—Provision of complex rehab technology is not a commodity. Each consumer of complex rehab technology has individual and specialized needs that require extensive customization for the individual's needs. These items are simply not appropriate for a competitive bid process that is designed to attract low-ball bids on commodity items. Most importantly, if items or services of sub-standard quality are provided, consumers' conditions will be exacerbated, requiring more extensive medical intervention. The bidding program is based on HCPCS codes, not individual products. Herein lays the conflict for applying bidding to high-tech rehab and assistive technology products. These products are uniquely configured for the individual consumer based on diagnosis, prognosis and lifestyle. Moreover, while products may be classified in the same HCPCS code, they are not equal in regards to their ability to meet the medical need of a consumer. Competitive bidding is not appropriate for high-tech rehab and assistive technology. By nature, rehab companies have a unique business model that involves a high level of personal involvement between the provider and consumer and the integration of licensed health care professionals throughout the process. These products and integrally related services are particularly ill-suited for the bid program because the bid program will result in DME suppliers reducing services and selecting products provided based on cost, not appropriateness. A reduction in services or limitation of products based on price alone which would result from competitive bidding, will have a severe negative impact on clinical outcomes associated with the provision of high-tech rehab and assistive technology.

Referral Impacts—Physicians and Hospital Discharge Planners

Physician referral sources as well as hospital discharge planners will be limited to referring beneficiaries only to the small number of contract suppliers in the bid areas. These contract suppliers are not chosen based upon the referral sources' preference; they may not be companies the referral sources are familiar with or have any assurance that their patients will obtain the care they need. Hospital discharge planners may have to wait longer period of time; requiring them to incur costs of longer hospital stays. These referral sources will likely have to arrange for services with multiple suppliers, since most did not win contracts for multiple product categories. Finally, referring physicians and hospital discharge planners will have no assurance that their patients will obtain the level of care they received in the past.

Summary of Unintended Beneficiary Impacts of the Bid Program

- The First Round of the bidding program will eliminate an estimated 71% of all suppliers in the first ten markets, including small, medium and large businesses. Many of these suppliers will not survive and will declare bankruptcy.
- Almost four million Medicare beneficiaries who may need DMEPOS are covered by the first ten competitive bid areas (CBAs). An additional 18 million Medicare beneficiaries will be impacted by Round Two.
- CMS' selection of a relatively small number of suppliers will result in an increase in ratio of beneficiaries to supplier of 339%—numerous winning suppliers will be overwhelmed by the huge increase in volume which their systems and infrastructure may not be able to handle.
- Almost 224,000 Medicare beneficiaries who currently rely on home oxygen therapy may experience a disruption of their service if their provider does not grandfather, and tens of thousands of new patients prescribed the therapy will have severely limited access from July 1, 2008 forward. As they assume ownership of their equipment in January 2009, they may have to switch providers in order to obtain portable oxygen.
- The largest oxygen patient bases impacted are located in Miami/Ft. Lauderdale/Palm Beach, FL; Riverside/San Bernadino, CA; Dallas/Ft. Worth, TX; Orlando, FL; Kansas City, KS/MO; Charlotte, NC and Cleveland, OH.
- Over 143,000 beneficiaries currently receiving home-delivered diabetic supplies may be forced to switch providers by July 1 since there is no grandfathering provision and few of the providers currently serving Medicare won bids. Small winners will be overwhelmed by the rush of patients to switch by CMS' deadline.
- Over 10,000 beneficiaries currently receiving home enteral nutrition therapy may be forced to switch providers by July 1 since there is no grandfathering provision and few of the providers currently serving them won bids.
- Over 16,000 beneficiaries currently being treated at home for Obstructive Sleep Apnea (OSA) may have to switch providers as they assume ownership of their equipment under the DRA.

- Almost 25,000 elderly beneficiaries currently relying on hospital beds to remain at home may have to switch if their providers do not grandfather due to irrationally low pricing in one or more markets.
- The 26% payment cuts, a significant reduction in revenue stream, will it difficult for contract supplier to obtain needed growth capital.
- Beneficiaries may be forced to sever long term relationships with their HME provider (particularly for beneficiaries with high end rehab and oxygen needs). Plus, beneficiaries will be forced to deal with increased paperwork (statements, deductibles) if they have multiple needs that will be provided by multiple suppliers. In addition, consumers will often be forced to choose a supplier they don't want.

Unintended Consequences of the Bid Program, Round One

- Ten major metropolitan areas will be directly negatively impacted with job loss and bankruptcies, starting July 1, 2008. Long-standing local companies who have offered quality homecare services for decades were excluded from participating, and will be forced out of business based upon government fiat. This will result in significant local market disruption.
- **Beneficiary Disruption**—Almost four million Medicare beneficiaries will be impacted by Round One, and an additional 18 million Medicare beneficiaries will be impacted by Round Two of the bid program. Beneficiaries have come to rely on the longstanding relationship they have with their home oxygen and DME providers. Not only will they be surprised to discover their long-time provider may no longer be able to serve them effective July 1, they will also be faced with obtaining services, equipment and supplies from *multiple* new suppliers (some of whom may not be local or experienced in providing the care they need).
- **Good Companies Arbitrarily Eliminated**—Many suppliers traditionally serving the initial ten bid areas did not win the bid for products representing their core business. It appears that many non-traditional and "long-distance" providers with little or no history serving these markets won bids, simply because they bid the lowest prices. Many of the winning bidders in these areas have no physical presence where they won the bid; they have absolutely no "skin in the game." With little other bid criteria, super low bid strategies worked to secure a winning position and potentially eliminating established and more experienced companies from participating. These winners are already contacting local providers who lost, with whom they wish to subcontract to serve these local markets because they have no physical presence in the market or competency in providing the products and services they won. The CBIC told many bid applicants that their bids were disqualified for technical reasons; no detailed explanation was provided and there is no appeal process allowed. We expect significant job loss and business bankruptcies in these communities. In a program designed in part to weed out unscrupulous providers, this "roulette" game will instead result in the financial demise or disqualification of some of the country's best providers on technicalities that cannot be corrected. They are shut out of the market for at least three years.
- **Winners Did Not Necessarily "Win"**—Even suppliers who won bids are seriously concerned that the deep payment cuts will make it impossible to remain financially viable and be able to serve beneficiaries throughout the three year contract period, given the magnitude of the payment cuts (26% on average). Because of the median price methodology, 50% of the winners must accept pricing below their actual bid. Many will have difficulty in obtaining additional working capital in the current credit environment. These cuts, combined with the upcoming January 2009 implementation of the Deficit Reduction Act of 2005 (DRA), will jeopardize patient access to care and services. Finally, winning bidders cannot even sell their businesses without government approval.
- **Program Threatens Long Term Viability of the Industry and Its Ability to Serve Beneficiaries**—As the industry's largest industry creditor, Invacare foresees significant chaos in the credit market for this industry given the tight margins that currently exist. Good customers who lost bids have become instant bankruptcy risks. It will also be difficult to provide winning firms with the credit they are seeking given the significant payment cuts. Inflation rates for certain provider costs have escalated since the bids were prepared and submitted almost a year ago (e.g., fuel), yet providers must live with the new rates for three years without any opportunity for adjustment.
- **Beneficiaries Will Suffer**—When suppliers are forced to establish an artificially low bid to obtain a winning contract, two things often occur to the disadvantage of the beneficiaries they serve. First, suppliers may substitute cheap-

er products and reduce the non-equipment services they have historically provided, as they must find ways to reduce their operating costs. Both the General Accounting Office (GAO) and MedPAC raised this concern specific to portable oxygen equipment, which CMS has identified and encouraged for its ability to reduce costs to the Medicare program as well as improve patient quality of life. Second, once budget pressures begin to set in for these suppliers, due to poor inflation projections or unexpected administrative costs from meeting capacity requirements, support services are eliminated, for example, services such as 24-hour on-call service, preventative maintenance, etc. Hospital discharge planners will be forced to place patients in the hands of suppliers with no track record of service. Further, a significant challenge for beneficiaries will be the fact that they will have to obtain competitively bid products from as many as nine different suppliers, depending on the products and services they need to treat their medical condition(s) at home. This is contrasted with their ability today to receive many services from a single, local provider.

Answers Needed From CMS

1. CMS' one-page notification letter and grid of wining/non-winning products, along with reason codes, was simply inadequate for a program of this magnitude. CMS must be held accountable for its decisions regarding which suppliers won contracts and which did not. There was zero clarity around how CMS determined each supplier's "capacity" and determined how many winners were needed for each market. Since CMS disqualified many bidders for supposedly not providing the correct financial reports (without giving them the opportunity to rectify the situation), **CMS must be fully transparent and publicly disclose the financial criteria it used to assess the financial information bidders submitted to CMS.**
2. **CMS must publicly disclose how it calculated the single payment amount for all the HCPCS codes in each product category in each competitive bidding area.** Some non-winning bidders lost by 1%, which represents pennies or dollars, and since CMS' definition of "capacity" remains unclear, arbitrary exclusions of high-quality, accredited providers occurred.
3. **CMS must explain why it relied on unsubstantiated "supplier-reported" capacity for growth** (as explained by Mr. Weems on the March 20, 2008 national conference call) and how it used that capacity data to determine the total number of winners needed for each market.
4. **If, in fact, errors occurred that were the fault of CMS and its CBIC contractor, will CMS/CBIC fix the errors and allow affected suppliers to participate?**
5. Since the Federal Acquisition Regulations are generally not applicable to this process (via the statute), **what legal basis exists for CMS' refusal to provide information related to:**
    a. The number of bids submitted in each product category for each of the ten areas?
    b. The financial criteria and review process that were applied to the supplier's financial information that was submitted?
    c. How CMS/CBIC calculated the single payment amount for each HCPCS code in each product category in the ten areas.
    d. How CMS determined that a provider with an office eight hours away could serve Medicare beneficiaries with home oxygen therapy?

Request to Congress

Given the high likelihood of significant negative impacts starting July 1, 2008, and the series of fundamental procedural flaws already identified (*see* Attachment), **we recommend that Congress suspend the bid program and work with the industry to establish a workable alternative system.**

Summary

This is a heavy handed government takeover of an industry, where CMS determines whether individual businesses live or die, CMS sets pricing, and controls an owner's individual right to even sell the business. This "Russian Roulette" process will be repeated every three years, steadily eliminating competition in the local markets until oligopolies/monopolies are established and ensuring that consumers have limited access to needed items. This is not the American way.

Attachment

Fundamental Procedural Flaws/Irregularities

Following is a summary of the types of significant procedural flaws identified since bidders were notified on March 21, 2008 of whether or not they were offered a contract in any of the products and areas they bid. It appears that so many errors have been made during this initial supplier selection process that it has resulted in numerous suppliers being improperly and unfairly removed from the bidding program. There is no due process associated with this program. If these errors are not addressed and Round One proceeds as is currently planned, Medicare suppliers and the beneficiaries who rely on their items and services will be irreparably harmed.

1. ***Many suppliers submitting bids were improperly and unfairly disqualified*** from the process because of missing data, according to letters they received. However, most of these disqualified bidders can demonstrate that they did, in fact, provide the proper data to CMS and should not have been disqualified.
2. ***Some suppliers were erroneously rejected*** because they supposedly did not meet the requirement that they were accredited when, in fact, these suppliers were accredited by the deadline.
3. ***MEPOS suppliers that were offered contracts were provided less than ten days from the postmark date to accept the contract.*** This is a very short period of time for a firm to evaluate the pricing impact and contract terms and conditions and determine whether they will accept the contract. Moreover, at the time they were offered contracts, winning bidders had no information regarding how many other suppliers were offered contracts in the product category, to determine how many competitors will be serving the market. This is critical information to determine whether the supplier can financially sustain the business at the bid rate.
4. ***In some product categories, identical bid prices were calculated for multiple bid areas, suggests flaws in the bid calculation process.*** Unless the median bid submitted for these HCPCS codes in these multiple markets was identical, this is highly improbable mathematically, based upon CMS' final regulation on the bid program. For example, in the high end rehab wheelchair product category, there are 105 codes whose prices are identical in 2 markets, 24 codes' prices are identical in 3 markets, and 14 codes' prices are identical in 4 markets. In the standard power wheelchair product category, there are 76 codes whose prices are identical in 2 markets, and 18 codes' prices are identical in 3 markets. In another example, the new single payment rate for stationary oxygen systems is exactly the same amount, to the penny—$136.90—in both Charlotte, NC and Pittsburgh, PA. Again, this is statistically highly unlikely.
5. ***Suppliers were rejected based upon criteria that were never communicated to bidders. For example, bidders submitted low prices for codes that had close to or zero utilization, to maximize the competitiveness of their "composite bid," upon which they would be compared with other bidders. These suppliers' bids for the entire bid category were thrown out, supposedly because these items bids were too low. In reality, if utilization is zero or very small, suppliers can afford this. This type of application of financial criteria was never publicized. It illustrates the subjective nature of the reviewers who evaluated the bids, their lack of familiarity with DMEPOS business operations and is contrary to the process CMS set up for suppliers to submit bids.***
6. ***On September 13, 2007, Twelve days before the bid window closed, CBIC changed the Request for Bids rules.*** The original RFB stated that "beginning 10 business days before the bidding window ends, suppliers will be notified if there are any missing hard copy attachments." Two days before the bid window closed, the CBIC web site document stated that "the system will remain open for at least 15 days after the bidding window ends to allow bidders to check the completion status of their electronic bids and verify receipt of hard copy documents by the CBIC." Therefore, at the last minute, the CBIC changed the rules without informing suppliers who had already submitted bids to require suppliers to verify receipt rather than the CBIC notifying suppliers if there was missing information.

For more information, contact Cara C. Bachenheimer, Invacare's Senior Vice President, Government Relations at *cbachenheimer@invacare.com*.

Statement for David Carey

Arizona Bridge to Independent Living (ABIL) is urging you to support H.R. 2231 and S.2931, which will exempt complex rehabilitation products and assistive technology products from the Medicare Competitive Bidding Program.

As an organization that promotes independence for people with people with disabilities we understand your concerns, however, a blanket approach is not the answer.

In Arizona, the number of Durable Medical Providers (DME) has dwindled as have the quality of service. Creating barriers to service and causing many consumers, as well as some of our staff members to wait months in order to get repairs to their mobility devices (i.e. power wheelchairs). Besides losing taxable income from being unable to work some individuals have developed secondary conditions that have required medical attention. Which as you know, drives up the cost in another area.

What we have now is a monopoly! A good approach would be to create an open market, which will create competition, manage costs and give consumers options to timely service similar to local automotive repair shops. Doing so will allow individuals to be productive taxpayers within the community, as well as remain healthy.

We urge you to ask your colleagues to support H.R. 2231 and S. 2931. On behalf of ABIL, your support is greatly appreciated!

Statement for Douglas T. Harris

Dear Chairman Stark and Ranking Member Camp:

Thank you for the opportunity to present these comments to your committee. I enjoyed watching the hearing and I am anxious to see what results will follow. The Scooter Store is the nation's largest supplier of freedom and independence to Medicare beneficiaries via scooters and power wheelchairs. We have been in business for nearly 20 years and have over 1300 employee-owners (40% of the company is owned by our employees in an ESOP). We have over 60 company owned and operated locations in 42 states. We are proud to have a long standing tradition of making proactive suggestions to CMS and Congress to improve the Medicare benefit and continuously struggle to partner with CMS to combat fraud and abuse. While there are many ideas I would love to discuss with your committee, I will limit these comments to your recent hearing on Medicare's bidding program for DME.

1. Members of the committee mentioned that the results of the bidding showed that "Suppliers are willing to take less, much less, than the current Medicare fee schedule". The committee's comment demonstrates that the committee is not fully aware of how the bidding process worked. Any bid that was not less than the current fee schedule was automatically disqualified. The results do not necessarily indicate that suppliers are "willing" to take much less than the current Medicare fee schedule, it simply shows that some bidders understood the rule put in place by Medicare for this process; bid lower or be disqualified. Further, it shows how terrified some bidders were about being put out of business by losing a bid for their core business as they bid to sell some products at a LOSS.
2. Members of the committee mentioned a possible legislative solution of setting aside the bidding process and resetting the fee schedule at these new lower prices. We believe this would completely destroy the integrity of a "bid" process. As Ms. King from GAO, and Mr. Weems from CMS testified, suppliers that followed the rules in this process understood that the primary incentives to bid low were to retain Medicare business and gain market share. The committee's suggestion would make the winning bidders compete with these new substantial price reductions, AND eliminate any potential for increased market share. Suppliers should be able to survive with lower prices if they at least have the potential of increased volume. The committee's suggestion would eliminate that simple economic reality. When Mr. Ryan from AAHomecare said "yes" to that suggestion, he was clearly speaking on behalf of the losing bidders and not necessarily the winning bidders.
3. The Chairman expressed concerns about methods The Scooter Store might use to supply oxygen services. While we appreciate his humorous point to Mr. Weems at our expense, we can assure you that any and all respiratory patients we serve will receive the highest quality equipment and services. As one of the largest DME suppliers in the country, we have an outstanding family of over

1300 employee-owners, with operations in 42 states. We have been accredited for almost 5 years for all DME items, and we will continue to meet and exceed CMS's highest standards. As noted later in the hearing by Administrator Weems, we meet all of the newly created higher standards for oxygen services. The Chairman also expressed concerns that we would be serving the beneficiary from hundreds of miles away. While our national headquarters are in New Braunfels, Texas, we also have over 60 company owned and operated facilities in 42 states.

4. Over 60% of the bidders were disqualified. The committee indicated that this must indicate some type of "systemic problem" with CMS' process. Clearly the other option that must be considered is that there are "systemic problems" with many suppliers. While we agree that CMS's online bidding tool was an absolute mess, it was not impossible; as evidenced by the other 40% that figured out how to make it work. CMS, Congress, and even some industry insiders have been advocating for many years that the entire DME industry needs to substantially raise its level of professionalism. We believe the high disqualification rate substantially supports that argument.
5. The committee questioned whether or not the bidding process would result in a reduction in the number of suppliers, and thus a reduction in competition. We do not think that will be the outcome. As an example: In 2006 for the Miami bid area there were approximately 900 suppliers that furnished "standard power mobility" equipment to approximately 5000 beneficiaries; or an average of about 5 sales per supplier per year. Under the new bid process there will be less than 20 suppliers servicing the same area. This process will prevent over 850 suppliers from selling standard power mobility in Miami, but it was also allow the winning bidders to average 250 sales per year and thus achieve an economy of scale that could possibly create an opportunity for even greater savings to CMS and the beneficiary in the future.
6. The committee asked an outstanding question about the pricing for Medicare Advantage (MA). If the structure of this bid was so good that CMS wouldn't change a single thing, then why not bid MA this way. Remember, the simple mechanics of this DME bid were that if you did not bid LESS than the current Medicare price, your bid was automatically disqualified. So, how do we have MA costs that are $150 Billion higher than if those beneficiaries were on straight Medicare? MA companies are allowed to bid higher than the current Medicare cost. CMS had one pricing rule for DME bidding and not for MA bidding. So, what does this have to do with the current hearing questions? Simple again. The Chairman made it clear under "Pay-Go" rule we must find a $6 billion offset to delay or correct the problems with the current DME bid. Delay Round 1 of the DME bid for 6 months to get the obvious problems resolved, and delay Round 2 until there is clear information about the success or failure of the Round 1 implementation, AND at the same time add this really cool new rule (bid lower than current cost or be disqualified) to the MA bid and you have SAVED $140 BILLION.
7. The committee asked questions about tracking high cost DME items with serial numbers as a way to prevent fraud and abuse. We believe this is an excellent idea. The standard CMS claim form already has an input box for the product's serial number, and thus it could be submitted with every bill. This would give CMS the first tool of its kind to avoid improper payment BEFORE they are made, instead of the current method of paying now, and chasing down overpayments later. I would love the opportunity to discuss this idea with you or CMS at any time.
8. Additionally, as a fraud fighting method we encourage CMS to immediately implement the $65,000 surety bond for DME suppliers that was already authorized over ten years ago in the BBA of 1997. Earlier this year a bill was proposed to raise the $65,000 bond limit to $500,000 since someone believed the $65,000 clearly wasn't preventing fraudulent suppliers from stealing money from Medicare. However, the big news should be that the $65,000 bond has never been implemented. The amount doesn't need to be raised. CMS just needs to enact the project. We urge you to require CMS to add this fraud fighting tool immediately.

Thank you again for looking into ways to make this bidding program work for everyone. If competitive bidding is done properly then CMS, beneficiaries, the tax payer, AND suppliers can win. If the bidding program is executed poorly, it might

get a good score from CBO, but it will wrongfully and unfairly hurt suppliers, CMS, and worst of all disabled beneficiaries.

Respectfully submitted,

Douglas T. Harrison
Founder and President
The SCOOTER Store
(830) 626–5802
The SCOOTER Store
1650 Independence Drive
New Braunfels, TX 78132

Statement of Ellen S. Durrence, Letter

The Honorable Pete Stark:

Please accept this letter as our formal request to submit our comments for inclusion in the record of the hearing on Tuesday, May 6, 2008.

As a small, local DME provider in Charleston, SC, we have several concerns relating to the implementation of the competitive bidding program. We met with our State Representatives regarding this program and they feel, as we do, that it is "Anti-American" because it will eliminate the patient's freedom of choice, eliminate competition, create a significant loss of jobs, and destroy small businesses.

We have served our community for more than 20 years and have provided much needed medical equipment to area residents, many of whom live in rural areas with little or no ability to access routine healthcare. We have established long-term relationships with many of these families and are concerned for their future ability to access a medical equipment provider if this competitive bid program is implemented. Additionally, we employ 35 dedicated people who take pride in delivering the much-needed items to our patients. We, with several other independent providers, are facing an imminent threat of losing both our patients and our employees.

Following are urgent, legitimate concerns for our patients as well as small business providers and employees:

Round 1 eliminated 65% of bidding applicants

Applicants were rejected for reasons CMS has yet to substantiate

Patients will suffer

Patients will be required to get a bed from one provider, a bed-side commode from another and a wheelchair from yet another provider

Access to Durable Medical Equipment providers will be extremely limited, some patients will be hours away from the nearest provider

Equipment standards will decline due to the significant reimbursement cuts; providers may supply sub-standard equipment in order to survive the drastic cuts

There is no assurance that the "winning" providers will be able to stay in business with these reimbursement rates. If they are forced to close, what provisions are in place to assure patient access? By this time, the "losing" providers will have already been eliminated from the industry.

More than 60% of the nation's independent providers will be out of business

Because independent providers do not have the backing of a large national chain, the independent providers are typically the ones willing to "go above and beyond" for the patients and are willing to reach the outliers

Thousands of jobs will be lost

Round 1 has already eliminated 2,500 jobs
Round 2 is estimated to eliminate 15,000 jobs

CMS administrative costs will absorb the majority of any "savings" projected

Please, I urge you to stop the competitive bidding process. The durable medical equipment providers are more than willing to work with CMS to help reduce costs,

however, this process will, inevitably, damage the industry and the patients relying on it.

Sincerely,

PHARMACEUTICAL HEALTH CARE
Ellen S. Durrence, R.Ph.
Vice President
Letter Submitted by:
Ellen S. Durrence, R.Ph., Vice President
Pharmaceutical Health Care

Statement of Eric Sokol and Stephen Azia, Letter

Dear Chairman Stark and Ranking Member Camp:

The Power Mobility Coalition (PMC), a nationwide association of suppliers and manufacturers of motorized wheelchairs and power operated vehicles, applauds the House Ways and Means Subcommittee on Health for holding a hearing examining the problems implementing the competitive bidding program for Medicare durable medical equipment, prosthetic and orthotic supplies (DMEPOS).

As numerous witnesses at the hearing testified, various bidding irregularities were identified and an inordinate number of suppliers were unfairly disqualified during the first round of bidding. According to the American Association for Home Care, nearly two-thirds of accredited qualified DMEPOS suppliers who submitted bids were disqualified in the first round.[1]

Moreover, single payment amounts for competitively bid DMEPOS items in the impacted Metropolitan Statistical Areas (MSAs) resulted in a 26% cut under current fee schedule amounts. For power mobility devices (PMDs), this translates to a 21% decrease across the ten impacted MSAs. This cut comes on the heels of a 27% reduction in PMD reimbursement when CMS established a new PMD fee schedule in November, 2006. In just 17 months, therefore, PMD reimbursement will have been reduced by nearly 50% in competitive bidding areas.

Even without these competitive bidding rates being implemented, utilization for PMDs has already been negatively impacted. According to CMS' own projections, 243,000 prescriptions for PMDs were expected to be written in 2007.[2] SADMERC data shows, however, that only 180,000 PMDs were provided by Medicare or 30% (57,000 beneficiaries) **below** CMS' own forecast.

As a result of these bidding irregularities, the possibility of systemic problems in the bidding process and the further cuts in DMEPOS reimbursement that threaten service and access, the PMC supports efforts to delay implementation of the program until the all problems and irregularities in the bidding process have been identified and resolved in a manner that will ensure beneficiaries access to high quality DMEPOS items.

In the alternative, the PMC offers the following recommendations to improve the competitive bidding program by establishing a more level playing field among bidders, compelling greater supplier participation and establishing safeguards to ensure beneficiary access. These recommendations include:

Increasing Transparency in the Bidding Process

The current bidding process is shrouded in secrecy increasing the mistrust between bidders and the Competitive Bidding Independent Contractors (CBIC). The PMC recommends that the CBIC share bidding methodology and criteria used to establish the single payer amounts in impacted MSAs. The PMC recommends that the CBIC release a report, shortly after it awards contracts in each bidding round, which sets out:

1) number of total unique bidders;
2) number of bidders awarded contracts;
3) criteria of how bidders financial statements were evaluated;
4) how utilization and capacity was evaluated;
5) was accreditation reviewed; and
6) how the single payment amount was calculated for each MSA.

Allowing Suppliers the Ability to Correct Minor Errors or Omissions

As numerous witnesses at the hearing testified, many suppliers were unfairly disqualified from the initial round of competitive bidding because of missing informa-

tion on their bidding application or confusion surrounding bidding instructions. Some of these applications could have been easily corrected and suppliers could have avoided disqualification if they had an opportunity to cure these applications prior to deadline. The PMC recommends that CMS instruct the CBIC to alert suppliers within 30 days of submission if their applications contain some minor errors or omissions and, further, provide suppliers with 10 days to make corrections and resubmit the application.

Establishing an Appeals Process

Under the competitive bidding rules, suppliers have no administrative or judicial review for "the awarding of contracts" under the competitive bidding program.[3]

The PMC has concerns that CMS can conduct the competitive program without any opportunity for administrative or judicial oversight of the process. Considering the number of procurements that are set aside each year by the General Accountability Office (GAO) and the United States Court of Federal Claims based upon government error, it is inconceivable that CMS would even suggest such a secret and insulated process. This is a recipe for arbitrary and erroneous awards.

Suppliers who have a reasonable grievance should be able to challenge a determination of the CBIC before an independent entity or Administrative Law Judge to ensure fairness and due process. Suppliers will be staking resources and, in certain instances, survival of their business on contracts awarded by the CBIC. As a result, suppliers must be afforded the right to contest questionable determinations. Further, to ensure no disruption in DMEPOS services to beneficiaries, any independent appeals process must be expedited.

As a result, the PMC recommends that Congress require any competitive bidding program to be subject to the traditional judicial review of procurements conducted by the government.

Providing COLA Increase for Single Payment Amounts

CMS should allow for cost of living adjustments (COLAs) to single payment amounts determined under the bidding process. COLA increases will ensure that suppliers are fairly compensated if costs increase as a result of inflation or other economic pressures. Such an adjustment, moreover, will ensure that suppliers won't have to cut back on quality or services in order to continue participation in the Medicare program and will aid suppliers in meeting capacity targets set out in the bidding contracts.

Monitoring Supplier Capacity and Allow the CBIC to Make Mid-Course Corrections

At the hearing, the GAO recommended that CMS closely monitor competitive bidding, through beneficiary and supplier surveys and other oversight, to ensure access and that contracted supplier's meet capacity. The PMC recommends that CMS give the CBIC the authority to contract with new suppliers if GAO reports potential beneficiary access issues as a result of suppliers failing to meet capacity for a particular product in a particular MSA.

Requiring at Least a 10% Savings Before a DMEPOS Item Can be Subjected to Competitive Bidding

Given the costs to the Medicare program in establishing and implementing the competitive bidding program, the PMC recommends that CMS exempt those items and services for which the application of competitive bidding is not likely to result in significant savings of at least 10%. This will ensure the outlays made by the Medicare in implementing a bidding process will pay off in a net savings to the program.

Prohibiting CMS from Extending Single Payment Amounts Beyond Competitive Bidding Areas

Under competitive bidding rules, CMS has the authority to extend single payment amounts for DMEPOS items to areas that have not been subjected to competitive bidding after 2009. The PMC recommends that Congress repeal this authority since reimbursement reductions in rural or underserved areas will further exacerbate beneficiary access and jeopardize the mostly small, "mom and pop" operations that serve these communities. Suppliers who serve rural and underserved areas have to travel great distances to service beneficiaries and often their costs are higher since they serve fewer patients and cannot take advantage of volume discounts.

Establishing a Serial Number Tracking Program for DMEPOS Items

CMS has characterized competitive bidding as an additional anti-fraud tool. Since the late 1990's, the agency has testified to Congress than more needed to be done to address fraud and abuse. In 2001, former Health and Human Services (HHS) Inspector General, June Gibbs-Brown testified to Congress that the two primary issues the Medicare faces with DMEPOS suppliers is paying for products never delivered and/or paying for more expensive items that what was actually delivered to the Medicare beneficiary.

Rather than punitively punishing legitimate providers by drastically reducing the fee schedule, the PMC recommends that CMS establish a serial number identification program that can track individual DMEPOS items through the claims process. Under such a system DMEPOS manufacturers could report serial numbers to be included in a CMS data base. Suppliers would then have to include the serial number on their claims, allowing CMS to monitor and track supplies from manufacturer to supplier to beneficiary.

The PMC appreciates the opportunity to comment on the establishment and implementation of the competitive bidding program for Medicare DMEPOS items. The PMC agrees with many members of the Subcommittee who question CMS' characterization of the program's implementation and urges Congress to delay any further implementation of the program or, in the alternative, implement the above-described recommendations.

The PMC wishes to note that the Medicare PMD benefit provides thousands of beneficiaries with freedom, independence and the ability to live healthier and more active lives. PMDs save the Medicare program resources by keeping beneficiaries with compromised or limited mobility out of more costly institutional settings and decreasing their need for hospitalizations by making them safer in their environments. We look forward to working with the Subcommittee on appropriate competitive bidding program safeguards to ensure that qualified beneficiaries maintain access to high quality DMEPOS items and services, including PMDs

Respectfully Submitted,

Eric Sokol
PMC Director
Stephen Azia
PMC Counsel

Statement of Ford C. Greene

SUBMISSION FOR THE RECORD

1. Please explain the rational for not letting everyone who will accept Medicare reimbursement for an item remain in the program and remain a provider. This decrease in providers WILL stop the advancement of NEW technology. In the Cincinnati MSA the three largest private companies who specialize in respiratory products and home oxygen are OUT of the Medicare program for three years. These three companies use the latest and smallest technology for it's patient's. The winning companies do not embrace this idea.
2. Competative Bidding WILL cost many job's in the MSA area's, effecting small business a disproportional amount!
3. Why were companies that did not have an office in the MSA allowed to bid?

Ford C Green
CEO
Green Respiratory Services Inc.
513–831–0507

Statement of Freeman H. Smith, Letter

Dear Chairman McNulty:

The American Subcontractors Association, Inc. (ASA) appreciates the opportunity to submit comments for the record on employment eligibility verification systems and the potential impact on the Social Security Administration's core mission of serving retirees, workers and people with disabilities. We would like to commend

the Subcommittee for its leadership on this important issue, and hope that our members' experience with work authorization might be useful as you work to determine the effects these new systems will have on SSA.

ASA represents more than 5,000 businesses who are primarily engaged in non-residential construction subcontracting. We are also concerned about the burden these employment authorization systems will have on SSA and believe that both the extent of the burden and the costs that will inevitably be born by SSA have not been adequately studied.

ASA remains committed to working with Congress to enact comprehensive immigration reform that will not unduly burden employers or Federal agencies. ASA's position on immigration reform calls for a comprehensive legislative package that:

- Addresses both future economic needs for workers through the creation of a guest worker program and practically
- addresses the estimated 7–11 million undocumented workers already in the United States.
- Creates an immigration system that functions efficiently for employers, workers, and government agencies.
- Creates a program that allows hard working, tax paying undocumented workers to earn legal status.
- Ensures that U.S. workers are not displaced by foreign workers.
- Ensures that all workers enjoy the same labor law protections.
- Strengthens national security by providing for the screening of foreign workers and creating a disincentive for illegal immigration.
- Strengthens the rule of law by establishing clear, sensible immigration laws that are efficiently and vigorously enforced.

Thank you again for the opportunity to submit comments for the record. I hope you will let me know if we can be of assistance as the Subcommittee works to address this important issue.

Very respectfully,

Freeman H. Smith,
Director of Government Relations

Statement of Greg Butchko, Letter

To Whom It May Concern,

My name is Greg Butchko. I own a Medical Supply company in Austin, TX that employs three full time employees, one part-time employee and a contract sales person. We are growing and expect to add another full-time employee this summer. I started the company five years ago after being laid off from a High Tech Company that I moved my family here to work for, which almost sent us into bankruptcy.

Although Austin is not scheduled to be in a competitive bid MSA until Round 2, I am extremely concerned with the information coming out as a result of the round one implementation of competitive bidding to date for a number of reasons:

- the overlooking of small providers
- a flawed certification/application process
- unfair bidder exclusions
- an excessively short period (10 days) for contract acceptance in round one

My greater concern is that should the commercial payors, which already pay at a reduced percentage of the Medicare allowables, choose to adopt these new rates, every item we sell will be paid below our cost. **We will have no choice but to shut down, and I will once again be on the street, looking for a way to feed my family.**

The House Ways and Means Health Subcommittee has scheduled a hearing on the Medicare bidding program tomorrow (Tuesday, May 6). The hearing will begin at 1 p.m. in the Longworth House Office Building. I hope that you or one of your staff will attend the meeting and let our concerns as a small business in your district be heard.

Sincerely,

Greg Butchko
Sungate Medical

Statement of Henry Ford Health System

Thank you for the opportunity to submit comments regarding the Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). I am Nancy Schlichting, President and CEO of Henry Ford Health System in Detroit, Michigan. I am also President-Elect of the Michigan Health and Hospital Association.

About eighteen months ago, Henry Ford Health System (HFHS) began collaborating with health systems in Michigan and other states in an effort to prepare for the eventual rollout of the CMS competitive bidding program for DMEPOS in 2008 and 2009. Our coalition includes Michigan's premier healthcare organizations, such as the University of Michigan, Beaumont Hospitals, McLaren, Sparrow, St. John's Health-Ascension, Munson, Mercy Memorial, Genesys Health System/Ascension and Oakwood Health. Michigan has many comprehensive health systems that have integrated the full continuum of care, including hospital, physician, home-health and DMEPOS services under a single health system entity. All hospitals and health systems in Michigan are not-for-profit.

Medicare and many private insurers, including Blue Cross of Michigan, have encouraged integration of care and reward cost-effective care management. Our experience demonstrates that DMEPOS services are vital to our ability to release patients from the hospital when they are clinically ready to go home, and secondly to prevent unnecessary readmissions. These are hallmarks of an efficient and cost-effective health system. In order to preserve our ability to integrate care, we are seeking legislation that will allow hospitals and health systems to provide DMEPOS services for our Medicare patients at a price determined through competitive bidding, without risking disqualification under competitive bidding.

The Medicare Modernization Act of 2003 directs CMS to establish competitive acquisition strategies for DMEPOS, which CMS has translated into a program of competitive bidding with contracts awarded based on price, capacity to serve a large number of patients and quality standards. During consideration of the final CMS rule in 2006 and 2007, we filed comments requesting consideration for the hospitals and health systems. The American Hospital Association made similar requests. No changes to address our concerns were made in the final CMS rule. We fully support the broad goals of competitive bidding on cost savings and improved quality for patients. However, we are concerned that the final CMS rule fails to recognize a continuing role for hospitals and health systems; similar to what has been provided for physicians and others.

Unlike DMEPOS vendors, physicians, hospitals and health systems are primarily focused on a broad spectrum of patient care. We are committed to doing what is best for the patient and to provide care in the least expensive setting. Home care and DMEPOS is an essential link in our strategies to provide safe and high quality care outside the hospital setting. Where patients and our hospitals currently can count on making one call to our own employees for all of the services covered by DMEPOS competitive bidding, we will now face an array of separate contractors for each of the ten services included under competitive bidding. The DMEPOS services are prescribed by physicians. Our hospital discharge planners work with patients and families to assure that everything is ready when the patient is ready to go home. The prospect of converting this efficient and cost-effective process of hospital discharge planning into what will necessarily involve a number of unaffiliated contractors is daunting and probably not feasible. Many of our Medicare patients leave the hospital with multiple DMEPOS requirements, such as a wheelchair, oxygen, surgical supplies, diabetic supplies and a bed. Coordinating this array of equipment and supplies among many contractors will destroy what is now a seamless process and introduce the opportunity for mistakes and unnecessary cost. Patients and families will face similar difficulties with the unbundling of services formerly available from us on a "one stop shopping" basis.

A key barrier to hospital and health system participation in competitive bidding is the CMS requirement that all bidders demonstrate their ability to serve all Medicare patients in very large regions defined through zip codes by CMS. The Henry Ford Health System includes 7 hospitals and the Henry Ford Medical Group, with more than 1,000 salaried physicians and researchers in 40 specialties. We provide care to more than 1 million southeast Michigan residents per year, and we employ more than 22,000 health care workers and professional staff. Although our hospitals serve large numbers of Medicare patients (33% of total payer mix at HFHS), we are not ready to provide DMEPOS services to all Medicare patients in this region without significant new investment, and we have no incentive to compete for DMEPOS patients from other Michigan hospitals. The final CMS rule does not provide a safe haven that would allow us to forge relationships with other health systems and cre-

ate regional hospital-based DMEPOS networks without violating anti-trust laws. Because our hospital-based DMEPOS services are owned and controlled by HFHS, which has more than $3.2 billion in annual revenues, the small business exemption for companies with less than $3.5 million in annual revenues does not apply. Our dilemma is similar to other health systems in Michigan and other states.

Most hospitals and health systems are preparing to file bids for some or all of the DME services subject to competitive bidding, even though we do not expect contracts. Our colleagues in states already affected by competitive bidding in 2008 report either disqualification or failure to win contracts. For example, the SUMMA Health System in Ohio, serving 9 hospitals, was disqualified. BayCare in Florida, serving 11 hospitals, was disqualified. Cleveland Clinic in Ohio, serving 9 hospitals, was disqualified. The University of Pittsburgh Medical Center, serving 13 hospitals in Pennsylvania was not able to bid low enough to qualify for a contract. These companies are part of our coalition of hospitals and health systems and require immediate help.

A losing bid or disqualification poses a huge threat to our hospitals and patients, as well as the communities that rely on us. The hospital is a key link in disaster planning, with our DMEPOS employees providing essential items and coordination that have proven effective for responding in the first critical hours of a natural disaster, such as flooding due to a hurricane (in Florida) or a terrorist attack (New York). Also, at Henry Ford, we are often called upon to provide DMEPOS services at no cost to patients who can't pay, along with home health services. We do this to help our patients, but also because the cost of equipment and supplies is often less than a hospitalization would be. These community benefits will be lost if hospitals and health systems are not allowed to participate in the Medicare DMEPOS program. CMS has no requirement that contractors participate in disaster planning or provide charity care.

CMS has estimated more than $1 billion savings to the Medicare program and patients as a result of competitive bidding. We believe this estimate should be revisited to also encompass the significant new inpatient costs where our hospitals are not able to discharge patients and where patients are readmitted due to the inability or unwillingness of an outside contractor to provide services on a timely basis. We are also worried about repairs and replacement of equipment that is needed to prevent fragile home-based patients from returning to the hospital. During the recent power outage that left the Detroit area without electricity for several days, for example, DMEPOS vendors advised home-based patients to call us or return to the emergency room for oxygen and other supplies until power could be restored and deliveries resumed. We were able to organize supplies with sister health systems in the Lansing area for these patients, even though we were not responsible for their DMEPOS services. If our hospital-based services cannot be maintained, this kind of safety net for DMEPOS services will disappear.

We do not believe a grandfathering for hospital-based DMEPOS services would in any way interfere with competitive bidding. For example, we have reviewed the CMS listing of the top 100 suppliers of Medicare DMEPOS services, which provide approximately 50% of all Medicare DMEPOS care to patients. Less than 1% of revenues in this top 100 group are part of a hospital or health system. The presence of hospital-based services in the marketplace is simply too small to adversely affect the number of bidders. Similarly, by accepting whatever pricing is determined through competitive bidding, we will actually contribute to the overall savings anticipated from the program.

The CMS rule includes quality standards for DMEPOS companies, which are long over-due. High standards are not new for our hospital-based DMEPOS services, since they are already subject to accreditation reviews by the Joint Commission on Accreditation of Hospitals (JCAHO), as well as transparency of business practices required under IRS rules, because they are part of our non-profit health system.

Our coalition of hospitals and health systems has come together to ask Congress for legislation that will preserve our role in providing DMEPOS services as part of our continuum of care. Because Medicare constitutes upwards of 30% to 40% of our DMEPOS service volume, we are not sure that we can continue this service without access to Medicare. Our coalition includes 60 hospital-based DMEPOS companies owned and controlled by health systems consisting of more than 225 hospitals in 23 states:

1. Alaska
2. Arizona
3. Colorado
4. Florida
5. Illinois
9. Michigan
10. Minnesota
11. Missouri
12. New York
13. North Dakota
17. Pennsylvania
18. Tennessee
19. Virginia
20. Wisconsin
21. North Carolina

6. Indiana	14. Ohio	22. South Carolina
7. Iowa	15. Oklahoma	23. Washington
8. Maryland	16. Oregon	

We respectfully ask the House Ways & Means Health Subcommittee to consider including in the Medicare package this year legislative language that preserves Medicare patient access to DMEPOS goods and services currently available through non-profit hospitals and health systems.

Respectfully submitted,

Nancy M. Schlichting
President & CEO
Henry Ford Health System
One Ford Place
Detroit, Michigan 48202

Statement of Hugh D. Durrence, Letter

The Honorable Pete Stark:

Please accept this letter as my formal request to submit our comments for inclusion in the record of the hearing on Tuesday, May 6, 2008.

I am a physician practicing family medicine in Charleston, South Carolina. As such, I see patients every day that have illnesses or injuries that can be treated easily in the patient's home. It is a good outcome for everyone; the patient desires to remain in his or her home and the government saves considerable money given this option in lieu of a hospital or facility stay.

Having said that, I am deeply concerned that the Competitive Bidding Program currently being implemented by CMS is threatening the "patient home option". As a physician, I foresee numerous challenges my patients and staff will face under this program.

Following are some of my concerns:

Patients, very possibly, will need to acquire home medical equipment from various suppliers. Typically, these patients are elderly and often times confused by the healthcare maze. Can you imagine an 80-year old lady coordinating the delivery of home medical equipment from 2, 3 or even 5 different suppliers for the husband she is caring for in the home? Couple that with the "invasion" of the suppliers' delivery technicians and the required documents each supplier will demand be completed upon delivery. You now have an overwhelming situation for the caregiver. I would also imagine that each supplier would demand the patient pay his or her deductible upon delivery. If equipment is being furnished by different sources, who will monitor when and if a patient has paid the deductible. For example, Company A is delivering a hospital bed and requires receipt of the patient's deductible amount. The patient complies, only to have the second supplier arrive moments later with the oxygen concentrator. They, too, demand a deductible from the patient because they have no confirmation that the patient has met the deductible with the first provider. This second provider will not leave the oxygen concentrator without payment because the reimbursement is such that they can't risk it. Now you have the patient paying duplicate deductibles with the hope of being reimbursed from Medicare some time later. These patients are often on fixed incomes. This has a great potential of being financially damaging to the patient.

Case workers, discharge planners and physician office staff will have an extremely difficult time placing equipment for patients if they are required to call several different medical equipment providers. Currently, hospital caseworkers and discharge planners are overloaded. Thus, they attempt to discharge the patient quickly in order to manage their caseload. They must ensure the patient's needs have been met when they return home. Under the Competitive Bidding Process, caseworkers, discharge planners and physician office staff will triple their already overwhelming workload by trying to coordinate the medical equipment with various providers. I foresee the "overloaded" discharge planner or caseworker taking "shortcuts" to get the patient out. This could be potentially damaging to the patient if appropriate equipment is not placed in a timely manner, or not at all. We could expect to see hospitals admissions increase as a result, thus resulting in increased government expenditures. I would also imagine we could expect to see increased patient health issues if the patient does not receive appropriate or adequate equipment when ordered.

Reimbursement rates have been reduced by an average of 26%. How can we expect a medical equipment provider to absorb such a significant cut? How will they remain in business and assure the patients get the necessary equipment? The providers offered a contract under this competitive bidding program must provide the equipment under these reduced rates for a period of 3 years. There are no accommodations for vendor price increases, economy fluctuations, employee wage increases or even cost of living increases. The providers that did not get awarded a contract will be long gone. What assurances are in place that contracted bidders will remain in business? The potential for complete loss of equipment access defiantly exists under the current Competitive Bidding process.

I, and many other physicians, am terribly concerned for the patient's ability to maneuver this process. I respectfully request your immediate action to stop the Competitive Bidding Program and implement an alternative cost-cutting option for the medical equipment providers.

Sincerely,

Hugh D. Durrence, R.Ph, M.D.
President

Statement of James T. Bragiel, Letter

Dear Congressmen,

The idea of competitive bidding for durable medical equipment sound good on the surface but, it WILL put many small suppliers out of business. My company is small compared to the nation-wide providers but we are average sized when compared to the multitude to oxygen providers throughout the nation. We have seven employees. We cannot even provide all the oxygen services to the city of Midland let alone the entire state. I cannot afford to staff or buy equipment to cover the state of Michigan, and I'm not sure I would even want to do it. I do understand that Medicare needs to save money and that there needs to be a reduction of prices, even if I don't like it. We now get paid less than half of what we did in 1997. I don't know of any other business that could survive if that reduction hit their company.

What I am asking for is to allow the small providers (less than 50 employee's) to accept whatever price the bidding decides and let those small providers continue to service Medicare patients. Please feel free to call me regarding this subject. My very existence as a business, and that of thousands of other suppliers, hinges on your decision.

Sincerely,

James T. Bragiel

Statement of Jann Sherin, BS, RRT, RCP, Letter

To the House Ways and Means Committee:

I am a Respiratory Therapist, and have been a therapist for 38 years, in homecare for the last 21 years. I was in healthcare when the first question that was asked of the patient was "What's your problem?" as opposed to today where the first question is "What's your insurance?"—And the insurance will determine your treatment and/or care. Maybe I am "old school", but as a healthcare worker, I resent it! What kind of treatment or care would you want for you or your relative? The sad fact is, "care" is exiting from healthcare.

In an industry that is driven by third party payments with less coverage for needed items, higher co-pays, or no pays, and medical facilities providing less care, we

are setting ourselves up for disaster. I have never seen an insurance reimbursement go up, however gas goes up, heat light and power goes up, landlords want increases, but our reimbursements keep going down. In homecare, we want to keep the patient out of the hospital, however with completive bidding; the patient is going to have no choice but to go to the hospital, then watch the healthcare cost! Completive bidding will only result in less care. Anyone can deliver equipment. Knowing how to use the equipment to its full capacity, reinforcing physicians' orders and educating patient and caregivers on disease processes and additional ways to manage their disease will be missing. Dr's spend 5–8 minutes with a patient. We spend whatever time is necessary to insure the patient and/or caregiver knows the uses, contra-indications, and gets the most from the equipment.

Large DME distributers view this as a distribution business. In my opinion by definition, this is a distribution and service business. The experts say things will be fine. I invite anyone and everyone on the committee to come see my America. Help patients decide on medication or food or rent, or electric because they can't afford it. Basics! Everyone wants studies. Come out with me and I promise not to let the facts get in the way. Please, I urge you to accept this invitation and see for yourself. Look at the people your decisions affect and explain your position. As an American, I realize that we are a nation of give and take. Time has come to stop taking from healthcare and give to the nation's assistance. Take care of your people. They make your Nation.

Thank you for your time to read this communication.

Sincerely,

Jann Sherin, BS, RRT, RCP
Clinical Director, NBN Infusions and Respiratory

Statement of Jim Buteyn, Letter

Dear Member of the Ways and Means Committee,

In the almost 20 years that I've been affiliated with DME industry I've never seen such sad and scary state of affairs as I do today in respect to the affects of Competitive Bidding on beneficiary care and access and the apparent deliberate attempt to put over 70% of the DME stores in this country out of business.

Fact:

CMS, through its CBIC contractor Palmetto GBA did not contact suppliers regarding missing documentation in their applications.

Palmetto GBA conference moderated by Cindy Dreher in June 2007. Page 13 of the document around the 3rd paragraph it states the following:

"If your bid is not considered complete, including hard copy documentation, you will receive an email advising you that your bid is not complete. This email is only telling you there is missing information. At this time there has been no evaluation of the accuracy or completeness of the information provided. The notification is simply letting you know whether or not we've received all necessary information."

Fact:

CMS, through its CBIC contractor Palmetto GBA silently changed the rule regarding contacting suppliers about missing documentation from their application. Suppliers around the country have before and after page prints of the CBIC web site to prove this. CMS, nor its contractor, did not disclose this rule change.

Fact:

CMS, through its CBIC contractor Palmetto GBA awarded bids to suppliers who had never previously provided the bid item. Beneficiaries will now receive equipment by untrained suppliers who will "muddle" their way to make the correct assessment of the beneficiaries' needs. More disturbing is that some of these bids that were awarded to suppliers who had never previously provided the bid item are for oxygen, a life-sustaining DME item!

Fact:

CMS, through its CBIC contractor Palmetto GBA offered 44 oxygen bids in the Miami MSA. The Miami MSA is currently served by 501 oxygen suppliers. A 91% decrease in oxygen suppliers will not only affect daily access by beneficiaries but is also in total disregard of Disaster Preparedness. When the next hurricane hits the Miami MSA 44 oxygen suppliers (if their business has not been affected by the hurricane) will not be able to meet the needs of thousands of beneficiaries prior to and after the hurricane. It is physically impossible. Further review of other bid items shows the same trend.

Fact:

CMS has been quoted that they disqualified 63% of all received bids due to missing documentation. Such a glaringly high number of applications missing documentation should have alerted the contractor that this figure was far beyond the normal 1–3% average and that they may have a problem with the submission system.

Fact:

CMS, through its CBIC contractor Palmetto GBA awarded bids to suppliers in states the supplier is not licensed to provide medical equipment in. CMS ignored its own rules on competitive bidding.

Fact:

CMS has ignored cost of goods increases that suppliers must absorb for three years, even if it means taking a loss on the bid item. Several bid items are already at or near cost due to the change in the current economy.

Fact:

By CMS's own admission, over 70% of the DME suppliers in this country will be closed by the end of the implementation of Competitive Bidding. This will be detrimental to beneficiary access and put thousands of citizens on the unemployment roll. I do not believe this was the intent of Congress.

Fact:

Some winning bid suppliers are already creating their own rules because they no longer have competition. They are doing this by refusing to deliver certain small inexpensive items to beneficiaries. With no competitors, the beneficiary does not have free access or choice. This type of conduct is the beginning of creating the monopoly which was forewarned by industry experts. When a monopoly is in place, prices go up, not down.

Fact:

Due to the sporadic awarding of bids beneficiaries will end up dealing with multiple suppliers for their medical equipment. These are the geriatric citizens of our country, many of whom are confused, very ill, or simply do not understand how the system works. They are used to going to their local DME store and obtaining everything the physician ordered. Under competitive bidding the beneficiary could potentially deal with three or more suppliers in order to obtain the equipment.

Fact:

The physician community is already frustrated and angry with the supplier community due to the amount of documentation CMS mandates the supplier must obtain from the physician. Under competitive bidding the documentation requirements will increase for the physician community because the physician will have to complete paperwork for multiple suppliers for the patient.

In closing, I would also like to state that in my opinion the implementation of this type of a program is of great grievance to the Medicare beneficiaries in this country. Each and every beneficiary signed a contract in effect with the U.S. government when the beneficiary agreed to pay a premium for Part B Medicare coverage. In return for their premium the government agreed to provide the beneficiary with open choice for their Part B services. The implementation of a competitive bidding program takes away the beneficiary's choice and essentially creates the largest HMO in this country, financed by the U.S. taxpayer. Beneficiaries who agreed to Part B services chose that option because they wanted choice. The option

for the beneficiary to use those same Part B premiums to participate in a Medicare HMO *already exists.*

Respectfully,

Jim Buteyn
Arrow Medical Mgmt.

Statement of Joe Fernandez, Letter

To whom it may concern:

My name is Joe Fernandez, the owner of Harrisonville Home Health Equipment, which has been serving Harrisonville and the surrounding rural communities since may of 2002. This prevents many of patients from having to travel into Kansas City to take care of their Durable Medical Equipment services. We provide an alternative to the bigger corporations. For example, we are a friendly face that they recognize and trust for all of their home medical equipment and repair services. We are a small business that treats each new customer as "family". They are not just another number to us. We provide a valuable service to the people in the Cass County area.

We find it difficult to compete with the large corporations but by offering friendly and quick service we have found our corner of the market. However, what Medicare has done with competitive bidding is completely unfair and unreasonable for the small business owners of America. **Competitive Bidding will force the small businessman out of business**. I have done every thing I could to stay in business. I became Joint Commission Accredited and I submitted my bids, only to get back bid disqualifications for all my bids. I received BSE–4: (Bidder did not submit along with its bid the applicable financial documentation specified in the request for bids). I called Medicare and found out specifically what I needed to send in for financial documentation very early in the bidding process. So I sent in the financial documentation along with all 5 of my bids. Harrisonville Home Health Equipment deals in many areas of medical equipment and supplies. We provide a valuable service to the community and physicians. However if we lose our contract with Medicare to supply Standard Power Wheelchairs, Scooters and Related Accessories **we will be forced into Bankruptcy** and we will have to close our business.

It doesn't make any since with the way the economy is right now to force a large volume of businesses into bankruptcy and increase unemployment for hardworking Americans. This is a big industry and it will have a big impact that will be felt everywhere in the United States. In most cases the government would step in and stop such a hostel take-over or prevent certain disaster for American businesses. But the government just wants to add kindling to the fire we our already under.

Thank you for your time

Joe Fernandez

Statement of Joel Israel, Letter

To whom it may concern,

I received an e-mail from HomeCare Magazine this morning advising me of this hearing to take place on May 6th.

It is my opinion that this whole Competitive Bidding process is nothing short of ridiculous. My DME business has been caring for people in my area for nearly 70 years, and between the cut backs and now the Competitive Bidding, I will probably be forced to close my doors, placing my staff on unemployment, and forcing myself into early retirement.

You seem to have completely overlooked the small business people, who have been around for very long periods of time, and have built long-standing relationships with local customers, their families, their doctors and therapists. This is something that most of the so-called "chain" stores can never hope to do.

Whatever happened to *patient care*?

My company employs 5 full time staff members. How can I possibly afford the thousands of dollars as well as the man-hours involved in the accreditation process?

Not to even mention the whole competitive bidding process? There is no way I could ever compete with the pricing that's afforded to these larger companies.

Respectfully,

Joel Israel, Owner
Best Care Medical Supply
61 Lakeview Avenue
Clifton, NJ 07011

Statement of Laura Cohen, PhD, PT, ATP, and Barbara Crane, PhD, PT, ATP, Letter

Dear Chairman Stark,

The Clinician Task Force (CTF) is writing to express member concerns and make recommendations regarding competitive acquisition for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Our group is comprised of a nationwide group of 39 members, primarily physical and occupational therapists, whose work involves providing complex wheelchair seating and mobility services to individuals with severe disabilities. All of our members care deeply about individuals with disabilities who require wheeled mobility and aim to ensure appropriate access to medically necessary technologies. Most members of the Clinician Task Force have over 15 years of experience practicing in seating and wheeled mobility evaluation, recommendation and training.

Overview

People with severe disabilities need individualized, custom-fit power wheelchairs and rehab devices. These complex rehab devices represent a very small percentage of the overall power mobility benefit. These devices differ greatly from standard power wheelchairs in technology and associated services required to provide these devices. In order to accomplish the medical and functional goals of this small population of Medicare beneficiaries, off the shelf products will not suffice; a wide variety of technologies must be available in order to meet the specific and unique needs of an individual. As clinicians involved in the provision of complex rehab devices to people with severe disabilities we believe that competitive bidding will no longer allow access to the variety of necessary features and options, and the extensive service component that produce highly customized equipment. While it is important to remain fiscally responsible implementation of this flawed program is incomprehensible. We request that Congress intervene by supporting a statutory exemption of Complex Rehab from the competitive bidding program.

Round 1 Issues

Now results of Round 1 of the CMS competitive bidding program are available revealing the following concerns:

1. the number of suppliers being offered contracts in any given CBA is too low to ensure adequate choice of supplier and timely access to technologies and services;
2. equipment suppliers inexperienced and unknowledgeable regarding complex power wheelchairs and rehab devices have been offered contracts leaving few, if any experienced suppliers in contracted areas to provide complex technologies to Medicare beneficiaries; and
3. single payment amounts established for the category of complex rehab technology are inadequate to provide access to the range of products within specific codes severely restricting beneficiary access to medically necessary, custom rehab power mobility, which is needed to meet a beneficiaries' daily mobility needs.

Inadequate access to contract suppliers

Supplier and Quality Standards do not require that a contract supplier have a physical location in a CBA or proximal to the Medicare beneficiary. Due to the custom nature of complex rehab it is our concern that Medicare beneficiaries will not have adequate choice of contract suppliers or timely access to contract suppliers. Loop holes in the Supplier Standards and Quality Standards have resulted in an alarming trend. Companies without local facilities or trained certified staff are predominantly the companies that have been offered contracts in multiple CBAs. Safeguards implemented have instead left out reputable companies with long track records of successful service provision.

Inexperienced suppliers without certified Assistive Technology Supplier Staff

It is alarming to CTF members to learn that the experienced suppliers that we have worked with providing complex rehab technology services for years have been left out of the competitive bidding program. We are told that many have not been offered contracts due to errors in application processing. Suppliers have been told that requisite materials submitted were missing from their application eliminating them from the program with no option for appeal. It is the Medicare beneficiaries that will loose when they can no longer work with experienced and certified ATSs that they have life long relationships with in regard to their complex rehab technologies. The combination of price reductions eliminating the related services that accompany complex rehab and the availability of primarily suppliers with little to no experience in complex rehab will completely disrupt the service delivery process.

Severely restrict product availability

It is apparent from the announced single payment amounts that beneficiaries will be denied access to the range of products included within specific code categories. Similar to the issues identified by CMS in relation to full support surfaces included in the bidding process for complex rehab technologies are not distinct enough and cover a variety of clinical applications, features, levels of adjustability and levels of durability. This lack of distinction makes applying competitive bidding to those codes difficult and complex.

It is apparent from the single payment amounts announced for Round 1 that pricing is based on the lowest product cost within a code category. More complex chairs, cushions and postural supports, within the same code, significantly exceed announced payment amounts. Contracted suppliers will not provide products that exceed their costs and therefore Medicare beneficiaries will no longer have access to a variety of product within a code category. Furthermore, there simply is inadequate reimbursement in most competitive bid areas (CBAs) for many bid items further restricting beneficiary access.

Negatively impact clinical outcomes

CMS requires Medicare beneficiaries to be evaluated by a licensed/certified medical provider (LCMP) to determine complex rehab technology needs. Yet the competitive bidding process undermines this requirement. The contracted supplier is not required to provide the specified product even when a LCMP specifies and justifies an item. The contracted supplier can substitute product for "comparable" product under the same code. The problem is that "comparable products" do not necessarily have the same distinct functionalities as the product specified as a result of an individual evaluation. Complex Rehab Products—chairs to cushions are not easily interchanged. As a result contract supplier substitution of specified product with product from within the same code will not result in a comparable system negatively impacting the functionality of the final system.

Beneficiaries provided with inappropriate product are prone to secondary medical problems such as pain, decrease in functional ability, pressure ulcers, aspiration, and orthopedic deformities. Costs associated with the treatment of secondary complications can range from medication to hospitalization and surgery. For instance the cost to heal an ulcer can range from $5,000—$40,000. The occurrence of secondary medical complications resulting from the provision of inappropriate bid products can easily negate any savings that may be obtained from the bidding program especially for complex rehab technologies.

Increased costs to beneficiaries

Beneficiaries in medical need of products that exceed the single payment amounts can obtain medical documentation from a medical professional indicating the need for a specific product however the contract supplier is not required to provide that product even if ample justification and rationale are provided. The Medicare beneficiary will need to go to each of the other contracted suppliers to determine if they can obtain the required product elsewhere. If all contracted suppliers refuse to supply the needed item (because supplier cost exceeds single payment amounts) the only other option the Medicare beneficiary has is to go to a non-contract supplier, sign an advanced beneficiary notice (ABN), and pay cash to obtain the product. Previously reimbursed products obtained by Medicare beneficiaries are now only available by self pay further constricting the DMEPOS benefit.

Medicare beneficiaries will only obtain access to the lowest cost products. Cheaper less robust products will be provided to Medicare beneficiaries. The final rule regarding competitive bidding does not require contract suppliers to repair beneficiary owned equipment, therefore, contract suppliers will not be required to service the

items they sell. And, since unreasonable bids were used to develop the single payment amount, other non-contract suppliers will not be able to afford to repair these items either, leaving Medicare beneficiaries struggling to find a supplier willing to repair their power wheelchairs or paying for repairs directly.

For the beneficiary who relies on a power chair for mobility, getting payment for a repair is almost secondary to getting the repair done in a timely and efficient method. Reliability of product is of primary importance to beneficiaries relying on power chairs.

Summary

By design the competitive acquisition program reduces cost to the Medicare program at the expense of product quality and access. It is clear from the published single payment amounts for round one that contract suppliers can only provide the lowest level product within each code category simply because supplier cost for most complex technologies exceed the single payment amounts in many codes.

We urge Congress to take the following steps:

1. Exempt complex rehab devices from the competitive bidding requirement as the cost savings resulting from competitive bidding will be derived from inferior equipment and a decrease in service resulting in devices ill-suited for use by those with severe disabilities. The average savings that Medicare will experience due to competitive bidding of complex rehab technology is much less than reported.
2. Exempt complex rehab from the competitive bidding program. Competitively bidding complex rehab technologies is inappropriate, undermines the evaluation by the licensed/certified provider and puts the clinical outcome of Medicare beneficiaries at risk.
3. Request an audit and report from CMS of all potential contract suppliers of complex rehab to ensure there is a physical location with full service repair facilities within the CBA in proximity to the Medicare Beneficiary and ensure that certified Assistive Technology Supplier staff is employed on staff **PRIOR** to announcing winning contractors.
4. Request that CMS conduct a thorough assessment of the variety of products in each HCPCS code compared to the single payment amount to ensure that beneficiaries will continue to have access to medically necessary products through a viable reimbursement structure and report back to Congress.
5. Mandate that CMS rescind the pricing established for replacement parts and allow the current fee schedule amount to be paid for replacement parts for power mobility devices to ensure beneficiary access to repairs.

In the end it is the Medicare beneficiaries in greatest need of power mobility that are harmed by a bidding program which may be applicable to "commodity" products being applied to "Complex Rehab Products". To date CMS has failed to pay attention to ongoing public comment and concern. Now we ask Congress to intervene.

These same beneficiaries are the ones that have been most affected by the many policy changes that have occurred over the past several years restricting access to power mobility devices in the name of fighting fraud and abuse. There needs to be a balance between fiscal responsibility and ensuring access to quality technologies for the beneficiaries that need it.

We appreciate your consideration of our requests and hope you understand our concerns. If additional information is required, please contact either Laura Cohen at 404–370–6172 or Barbara Crane at 860–529–4936.

Sincerely,

Laura Cohen PhD, PT, ATP
Barbara Crane, PhD, PT, ATP

Statement of Manyvone Champavannarath

In my opinion the system is never going to be right. The people who are making these decisions will never understand what people with disabilities go through every day. All they see are words and numbers on paper.

I challenge each person who is making the decisions to think about the following when making decisions: Imagine you are a quadriplegic and have limited services. Can you imagine what it's like having to depend on someone for everything? Can you understand how it feels to have to wait for four hours to use the bathroom? Do you know what it's like to sit in your own excrement for hours? Can you under-

stand how disgusting that feels? Can you imagine having to ask a stranger to help you get a coke at the store? Imagine being hungry and not being able to get something to eat for yourself. Can you imagine what it's like to have your stomach growl and you cannot do anything about it? Can you understand what it's like to drool and not be able to wipe your own face? Imagine what it's like to have your eyes burn and not be able to do something about it. Can you imagine what it's like to sit at the computer and not be able to turn on the lights when it gets dark? Imagine what it's like to come home and not able to do anything until a staff person comes on duty. Can you understand what it's like to drop something on the street and you cannot pick it up? Imagine having to wait for a stranger to come by and then you have to ask that stranger to pick up the thing you dropped. Imagine being alone and have your nose itch and you cannot scratch it. Imagine what it's like to be in one position for fourteen hours a day. These questions need to be considered when decisions are being made regarding the disabled.

Please do not tell me that you understand because you truly cannot understand unless you are disabled. No one understands unless they are disabled or have taken care of a person with disabilities. Don't get me wrong—I love my life, but the system makes lives for people with disabilities tremendously more difficult than it already is.

Manyvone Champavannarath
Area 14

Statement of Matthew J. Rowan, Letter

Dear Chairman Stark:

Thank you for holding the Health Subcommittee hearing on May 6 regarding Medicare's competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). On behalf of the Health Industry Distributors Association (HIDA), we appreciate your consideration of the following comments for the record. HIDA is a nonprofit trade association representing approximately 200 distributor companies that provide medical-surgical supplies and equipment to numerous hospitals, nursing homes, and home health agencies across the United States. Our members account for roughly 80 percent of the medical products distributed through the healthcare supply chain. The competitive bidding program will significantly impact providers that serve Medicare beneficiaries in the nursing home, homecare, and extended care markets.

HIDA strongly recommends that the Centers for Medicare and Medicaid Services (CMS) postpone the July 1, 2008 implementation of Round 1 in order to address procedural flaws surrounding the implementation of the DMEPOS competitive bidding program. We also ask the agency to delay further implementation of Round 2 until the effects of Round 1 can be fully evaluated. With administrative spending becoming one of the fastest growing expenditures in healthcare, HIDA feels that Congress needs to evaluate the projected vs. actual administrative costs thus far associated with implementing the competitive bidding program. In the final rule 42 CFR Parts 411 and 414, CMS estimates internal costs and costs to its contractors to be approximately $1 million in immediate fixed calendar year costs for contractor startup and system changes for Round 1. HIDA believes that the analysis in the final rule significantly underestimates the actual administrative costs associated with implementing the program, therefore further reducing the program's net savings.

1. Medicare beneficiaries are poised to face disruptions in service, in addition to reduced quality. In an effort to preserve their business opportunities with Medicare, suppliers may substitute products with lower quality and less expensive equipment and reduce the non-equipment services they historically provided as part of the bidding package of home medical equipment and services. This occurs as suppliers strive for ways to reduce operation costs. Suppliers are beginning to feel the impact of the lackluster economic conditions currently afflicting the country. Costs associated with the price of raw materials needed for packaging, nutrition, and transportation have escalated since the September 25, 2007, Round 1 bidding deadline. Financial pressures on suppliers may result in a reduction of support services that have been traditionally offered to beneficiaries, or planned for prior to the increase in production costs. Hospital discharge planners will be forced to either place patients under the care of suppliers with no established track record of service, or to delay discharge. Additionally, a significant challenge facing beneficiaries will be obtaining competitively bid products from multiple and unfamiliar contract

suppliers, depending on the types of home medical equipment services and items that are needed.

2. CMS must allow more time to educate beneficiaries on the effects and resulting changes of the competitive bidding program. It has been projected that close to four million Medicare beneficiaries will be impacted by Round 1 of the competitive bidding program. With the apparent lack of beneficiary education tools in place prior to the Round 1 implementation date, the program will inevitably undermine access to quality care for millions of beneficiaries that rely on the Medicare Part B benefit. The current implementation timeline indicates that CMS has only allowed one month to bring Medicare beneficiaries up to speed on the impact of the program. The current timeline will cause confusion and interrupt the continuity of care for beneficiaries. Unless Round 1 is delayed, and proper steps are taken to adequately educate beneficiaries, CMS will be forced to inform patients and physicians that their Medicare beneficiary access will suffer as they can no longer utilize their current provider on most supplies.

3. The contract evaluation process needs to be re-evaluated. Medical-surgical suppliers with winning bids were only allowed ten days to assess the contract. However, the competitive bidding implementation contractor (CBIC) had six months to review the bids. This is a very short period of time for a supplier to evaluate the pricing impact, contract terms and conditions and determine whether they will accept the contract. Moreover, winning bidders have no information regarding how many other suppliers were offered contracts in the product category, to determine how many competitors will be serving the market. This is critical information to determine whether the supplier can financially sustain the business at the bid rate.

Furthermore, an alarmingly high number of legitimate long-standing companies who have been offering extended care and homecare services for decades were unfairly disqualified from the program for reasons that appear to be erroneous. Reports from various suppliers indicate that the CBIC has made serious errors that led to disqualifications of round one bids in nearly all of the first ten bidding regions. Disqualification from the supplier selection process has serious ramifications for Medical-Surgical providers, and CMS needs to immediately develop a diligent and thorough review process to ensure that all disqualification decisions are valid. Those who have been improperly disqualified need to be readmitted into the contracting process.

4. Further implementation of Round 2 needs to be delayed until Round 1 can be properly assessed. On January 8, CMS announced 70 additional metropolitan statistical areas (MSAs) and eight product categories for the second round of the competitive bidding program. Moving forward without a thorough evaluation of Round 1 will limit the ability of suppliers to continue to serve key providers and patients—a dangerous process that will have negative effects on patient and provider choice and the downstream quality of care. The program may also force suppliers to serve markets where they have no experience—a shift that's poised to significantly diminish the quality of service and patient care. CMS must carefully evaluate phase one of the competitive bidding program in order to ensure that subsequent phases are successful and implemented in a rational and logical manner. CMS must use beneficiary surveys, as well as supplier surveys, to evaluate the success of Round 1 and share this information with the provider community and the public, solicit feedback, and make necessary changes to improve the developing program.

5. Long term care (LTC) facilities should be excluded from Round 2 of the DMEPOS competitive bidding program because the Medicare Modernization Act addresses the delivery of products and services in a home health care setting. Nursing homes are a very unique setting compared to home care:

- LTC distributors prepare unique utilization and control procedures to conform to each nursing home's needs, which are integrated into their clinical staff requirements.
- LTC distributors' products are standardized to all residents based upon each nursing home's specific clinical protocol.
- Product availability is a major requirement for a provider serving a skilled nursing facility (SNF). A typical LTC distributor carries ample DMEPOS stock to service the Part B patient's and non-Part B patient's requirements of all SNFs in their MSA. A typical LTC distributor has 20,000–40,000 square feet of storage and stocks all major manufacturers and formulas. The LTC distributor has the "safety stock" to respond to multiple emergency requests for DMEPOS from multiple SNFs within hours. Home care providers do not have the storage, or the "safety stock," to respond in less than several days. These shortcomings are a clear detriment to the patient.

DMEPOS suppliers that serve these two separate and distinct end-users are well-qualified and experienced in their specific markets. To force one or the other to serve both end-users will result in confusion, errors, and the failure to serve patients adequately. In addition, CMS allowed LTC facilities to "opt out" of the DMEPOS competitive bidding 3-year demonstration projects in the chosen MSAs. Given this information, it appears clear that CMS recognizes the difficulties in requiring LTC facilities to adhere to the same requirements as a home care setting.

6. The citing of competitive bidding site demonstrations as beneficiary "quality and access success stories" for the program is inaccurate. The bidding that occurred during the demonstration projects in the Polk County, Florida and San Antonio, Texas MSAs were served by current beneficiaries that were grandfathered in using their current supplier. This is the reason that no complaints or problems with beneficiary access were recorded, as the demonstration project only affected new patients in these areas. HIDA strongly believes that without implementation of the changes above, the competitive bidding program is poised to limit the ability of suppliers to continue to serve key providers and patients—a dangerous process that will have negative effects on patient and provider choice and the downstream quality of care. CMS needs time to examine the issues that HIDA has risen on behalf of our member companies participating in competitive bidding. The integrity of the competitive bidding system, Medicare beneficiary access, and the financial viability of medical-surgical distributors are at stake.

HIDA appreciates the Subcommittee's proactive approach and we look forward to working with Congress and CMS on this critical issue. Thank you for taking the time to review our concerns and consider our comments.

Sincerely,

Matthew J. Rowan
President and CEO

Statement of National Association for the Support of Long Term Care (NASL)

The National Association for the Support of Long Term Care (NASL) submits this statement for the record in connection with the Ways and Means Subcommittee on Health hearing on May 6, 2008 regarding the Medicare competitive acquQisition program for Part B items and services.

NASL is a national trade association representing providers of ancillary products and services to the long-term care and home care industries. Our member companies provide medical equipment, as well as therapy services, diagnostic services, software systems and other ancillary services, to those care settings.

The focus of this hearing was the new competitive bidding program for medical equipment, prosthetics, orthotics, and supplies (DMEPOS), created by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173). The Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Humans Services (HHS) issued final regulations in April of 2007 implementing the program. Currently, the first phase of the program (Phase 1) is slated to begin on July 1, 2008 for ten product categories in ten of the largest metropolitan statistical areas (MSAs) in the country. The program is scheduled to be expanded to seventy additional MSAs in 2009 and to additional areas after 2009.

Our statement may be summarized as follows:

1. **The competitive bidding program is likely to impair beneficiary choice and access to care because the limited number of "winning" suppliers probably do not have the capacity to serve all beneficiaries in the competitive bidding areas.** CMS grossly miscalculated the number of suppliers that would submit bids and we are concerned that many of the "winning" suppliers may lack the expertise, knowledge of the localities and overall capacity to adequately serve entire competitive bidding areas.
2. **Long-term care facilities should not have been included in the program.** Despite the fact that Congress's clear intent and the entire legislative debate on the competitive acquisition provisions of the MMA were focused on home care, CMS decided to include the nation's long term care facilities ("LTC facilities" or "nursing facilities") in the very first phase of the new, largely untested program. In particular, this will affect the provision of enteral nutrition (tube feeding for patients who cannot take food orally and/or digest and absorb

adequate nutrition from traditional nutrient sources), the product area where there would be the biggest impact on LTC facilities in the first phase of the competitive bidding program.

3. **The median price methodology utilized to determine the "winning bids" is flawed.** Under the median price methodology, half of the "winning bidders" will be reimbursed at a rate below what they bid. This untested method is dramatically different from the approach used in the pilot programs and has the potential to negatively impact both access to and quality of DMEPOS items and services.

NASL supports fully the Congressional goals of promoting high-quality care for Medicare beneficiaries while achieving improved management of costs. However, we are worried that immediate implementation of the program without modification likely will limit beneficiaries' access to and choice of quality DMEPOS. We also are concerned that application of this program to DMEPOS provided to patients in LTC settings will not only fail to meet the goals set by Congress, but will unfairly disadvantage small suppliers that have special expertise in supplying these necessary items to LTC patients and thereby harm patient care. We believe that Congress should rethink the competitive bidding program, and at a minimum, we appeal to Congress to delay its implementation.

1. Medicare Beneficiaries' Access to and Choice of Quality DMEPOS will be Limited because the Low Number of "Winning" Suppliers Lack the Established Capacity to Fully and Effectively Provide DMEPOS Items and Services.

NASL believes that beneficiaries' access to and choice of quality DMEPOS will be impaired if the competitive biding program is implemented on July 1. Only 1,335 bids across the ten product categories in ten MSAs were ultimately selected as "winning bids," representing 22 percent of the 6,209 bids received by CMS. The number of bids actually received and selected by CMS pales in comparison to the 15,973 bids that CMS anticipated receiving and CMS' estimation that a bidding supplier would have a 60 percent chance of being selected as a winning bidder in at least one product category. *See* 72 Fed. Reg. 17992, 18069, 18080 (April 10, 2007). Beneficiaries' access to care and choice of suppliers will be limited due to the small number of suppliers that will be involved in the program.

In addition, it appears that many of the suppliers that have been offered contracts are *not* the current primary providers of DMEPOS in the competitive bidding areas. For that reason, it appears that CMS is in effect turning the DMEPOS program over to suppliers that were previously unable to succeed in the market. As a result, many beneficiaries will experience a disruption in their services as they are forced to transition their care to new DMEPOS suppliers in less than two months. The capacity of these suppliers to provide quality items and services remains largely unknown and therefore poses an excessive and unnecessary risk to Medicare beneficiaries.

In reviewing the suppliers' capacity issue, we look at three elements: 1) a supplier's expertise, 2) a supplier's experience in particular geographic areas and 3) whether a supplier can adequately service an entire competitive bidding area. Several of the suppliers awarded contracts have admitted that they do not have the expertise in the product category that they were selected to service. Due to the complexities involved with providing DMEPOS items and services, expertise in supplying one product category does not translate to proficiency in supplying other types of items and services. In addition, a surprisingly high number of the suppliers that were awarded contracts do not have experience with the geographic regions they will be serving. This lack of familiarity with the locality has to affect their ability to effectively serve the beneficiaries in the area. Finally, the ability of each "winning" supplier to provide quality DMEPOS items and services to an entire CBA is still an open question. Many of the suppliers awarded contracts are small in scope and may not have experience providing items and services across a broad service area.

Clearly, there does not appear to be a nexus between the suppliers that were awarded contracts and their expertise, experience in particular geographic areas or whether they can adequately service an entire competitive bidding area. This raises serious questions about the suppliers' abilities to successfully service the beneficiaries in their competitive bidding areas. It is puzzling how CMS can be sanguine with respect to access, quality and choice in light of its miscalculation related to the bidding process and its aftermath.

As a trade association representing suppliers with experience in providing DMEPOS to Medicare beneficiaries, NASL is highly skeptical that the items and

services can be provided as anticipated due to basic uncertainties related to the number of suppliers and the overall capacity of participating suppliers. It seems unreasonably risky to gamble with beneficiaries' access to and choice of medically necessary DMEPOS, as well as the quality of items and services that they will be receiving, by having the vulnerable elderly and disabled populations participate in a program with so many untested and unknown aspects. *CMS, and Congress, should act on the basis of facts, not assumptions that have no precedence.*

2. The Competitive Bidding Program Presently Cannot Address the Unique Challenges of Providing Medical Equipment and Services to Patients in Long Term Care Facilities.

Most Part B items and services within the scope of the competitive bidding program are provided in a home care setting by suppliers who focus on the home care market and may not have the familiarity or expertise to service residents of a nursing facility. As a result, the program was developed based on a home care model, which generally involves a distribution process designed for beneficiaries who are mobile and not institutionalized. However, the clinical needs of patients using enteral products in LTC facilities, how these products are distributed in the LTC setting, and the particular quality standards applicable to nursing facilities are quite distinct from the home care setting.

LTC Facility Patients Have Special Needs.

Residents in LTC facilities are usually older and more impaired than home care patients, often admitted after an acute care stay or unsuccessful home stay, and require a different regimen of care. For example, more than 80 percent of all enteral patients residing in LTC facilities require an enteral pump for safe delivery of nutrition, while less than half of all enteral patients residing in their home have such a need. LTC facility residents often have multiple clinical conditions, significant physical limitations, and the need for assistance with activities of daily living. In short, they often require a range of services beyond enteral nutrition.

LTC Facilities Have Special Relationships With Patients and Third-Party Suppliers.

LTC facilities have a special relationship with their residents. These facilities assume responsibility for coordinating the work of an array of clinicians, providers and suppliers to meet residents' healthcare needs. Indeed, LTC facilities are subject to Federal requirements mandating that "each resident must receive and the facility must provide the necessary care and service to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. Part 483.

Items furnished to LTC facility residents typically are furnished by either the facility itself or by highly specialized suppliers working in a close clinical relationship with the facility's nursing personnel. The level of clinical management and services related to the furnishing of DMEPOS to patients in institutionalized settings is substantially higher than that for non-institutionalized patients. In fact, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) publishes separate Standards for Tube Feeding for the home care versus nursing facility setting. As a result, LTC facilities working with third-party suppliers traditionally have established longstanding relationships with selected suppliers based on experience, trust and respect for their level of professionalism. We believe it is critical that these facilities continue to have the ability to select a supplier that meets performance and service criteria necessary for the needs of their patients. The competitive acquisition program could force nursing facilities to use unfamiliar suppliers and potentially interrupt ongoing relationships and established and functioning care plans that have worked to the benefit of their residents.

Applying the Competitive Bidding Program to Products Supplied to LTC Patients Will Not Fulfill the Purposes of the Program.

The use of competitive bidding to set prices and pay for therapies provided primarily in a LTC setting has not been tested sufficiently or successfully. CMS previously conducted a DMEPOS competitive bidding demonstration to test the feasibility and the program impacts of using competitive bidding to set prices for DMEPOS. CMS included only one therapy in the demonstration where the majority of patients are in a setting other than the home (i.e., enteral nutrition). The agency ultimately removed enteral nutrition from the first demonstration project and concluded it was not well suited for competitive acquisition in its final report to Congress, due to the complexity of the nursing home setting. Importantly, there was no conclusive evidence that competitive bidding would produce any clinical benefits for residents of nursing facilities.

There is Precedent for Treating the Long Term Care Setting Differently Under Medicare.

There is precedent for treating the coverage and payments of items and services provided to residents in LTC facilities differently than those provided to other beneficiaries—namely, in the Part D prescription drug benefit. CMS' regulations implementing this benefit artfully distinguish between providing drugs to the general Medicare population and providing those same drugs to Medicare beneficiaries in a LTC facility, subjecting pharmacies that serve LTC facilities to different quality and performance criteria than other pharmacies and providing distinct payments. According to CMS, providing drugs to LTC residents requires "special attention to ensure the unique needs of the vulnerable population are met without compromising the quality of pharmaceutical care." *Issue Paper #26, High-Quality Access to Long Term Care Pharmacies* (Jan. 21, 2005). Until now, CMS has consistently recognized the unique needs of nursing facility residents in receiving covered benefits under Medicare law.

3. The Median Price Methodology Utilized to Determine the "Winning Bids" is Untested and Unsound.

Under the median price methodology used to determine the "winning bids," half of the "winning" suppliers will be reimbursed at a rate *below* their bid. The median price methodology is dramatically different from the approach used in the pilot programs, which *averaged* the adjusted bids in the competitive category to determine the payment amount. *Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies* (2004). Additionally, the median price methodology is not observed in any other Federal bid construct.

Therefore, contrary to CMS' continuous assertion that the pricing methodology has been proven effective, the median price methodology is, in essence, an untested initiative. Additionally, the demonstration project included a vigorous ombudsman and beneficiary response mechanism, which cannot be replicated in the competitive bidding areas.

Although many of the "winning" suppliers may choose to participate, beneficiaries' access still could be negatively affected if "winning" suppliers are unable to provide quality items and products to all of the beneficiaries requiring services at amounts below their submitted bid prices. Additionally, it would be tragic if the quality of DMEPOS items and services were sacrificed in order for suppliers to meet the demand in each MSA at an insufficient price. The potential for harm to beneficiaries due to reduced access and quality is heightened by the absence of the beneficiary protections that were present in the demonstration.

Request for Congressional Action

NASL and several other organizations have raised the concerns outlined above with CMS in detailed comments responding to the proposed rule to implement the competitive bidding program. Unfortunately, CMS did not effectively address these concerns in finalizing the rule and is clearly determined to implement Phase 1 on July 1. Because of the enormous risk the competitive acquisition program imposes on beneficiaries, we ask Congress to delay Phase 1 until the Government Accountability Office has conducted an analysis of the impact of the reduced supplier pool and capacity issues on beneficiaries' choices and access to quality care.

We also ask that Congress act to limit this competitive bidding program to those services where it makes sense and to exempt nursing facilities. This exemption would be consistent with congressional intent and the plain language of the Social Security Act creating the competitive bidding program. LTC facilities already purchase DMEPOS through what is essentially a private competitive bidding process. There is nothing to suggest that Congress intended to undermine institutional purchasing power or replace the current private system with a public system.

For further information, please contact Peter C. Clendenin, Executive Vice President, NASL.

Statement of National Association of Chain Drug Stores

INTRODUCTION

Thank you for allowing the National Association of Chain Drug Stores (NACDS) the opportunity submit a statement on the impact of Centers for Medicare and Medicaid Services' (CMS) competitive bidding program for Durable Medical Equipment,

Prosthetics, Orthotics and Supplies (DMEPOS) on Medicare beneficiary access to life-saving DMEPOS items and services from their local community pharmacies. NACDS represents approximately 200 companies operating retail pharmacies in virtually every community in the country. NACDS represents national companies with thousands of retail pharmacies as well as local chains that operate as few as four pharmacies. Regardless of their size, all NACDS members are very concerned about the competitive bidding program and the potential impact it will have on Medicare beneficiaries' health.

Medicare patients obtain coverage for DMEPOS through the Medicare Part B program. Durable medical equipment includes such items as diabetic testing supplies and monitors, walkers, hospital beds, wheel chairs, and oxygen equipment and supplies. Many Medicare beneficiaries obtain these supplies from their local pharmacies. In fact, a recent study conducted by HealthPolicy R&D found that nearly two-thirds of older diabetic patients obtain their diabetic test strips from their retail-based community pharmacies.[1] Retail pharmacies are the largest providers of DMEPOS services to Medicare patients and are in a unique position to assist patients with their care and treatment and to monitor disease trends and therapy outcomes. In many cases, a pharmacist is the most readily accessible health care provider in the community for the Medicare beneficiary. One-on-one patient-pharmacist consultations can often provide the first opportunity to identify chronic illnesses and changes in patient conditions, and these consultations often result in early detection, referral, and treatment. In addition to helping to preserve the patient's health, early detection and treatment provides tremendous savings for the Medicare program. For many of these patients, the pharmacist serves as a gatekeeper assisting them and their caregivers in their health care management needs. Continued participation of community retail pharmacies in serving Medicare patients should therefore be an important consideration in the Medicare program.

RECOMMENDATIONS TO ENSURE BENEFICIARY ACCESS TO HIGH QUALITY PRODUCTS AND SERVICES IN THE MEDICARE DMEPOS PROGRAM

We raise the following concerns and offer our recommendations to help the Committee ensure that Medicare beneficiaries have access to high quality products and services from their pharmacies. First, CMS' requirement for DMEPOS supplier accreditation creates significant administrative and financial burdens for pharmacies. Congress should require CMS to exempt state-licensed pharmacies from this onerous requirement. Second, expansion of the competitive acquisition program for DMEPOS to include diabetic supplies sold at retail, or CMS' plan to establish national or regional competitive bidding areas for mail-order diabetic testing supplies, could limit participation by pharmacies and reduce diabetic patients' access to life-saving supplies and services. Thus, diabetic supplies sold at retail should not be subject to the program and CMS should not expand the mail-order program to include these products. Third, we ask Congress to reject any cut and/or freeze to the DME fee schedule update as an offset for a delay of the competitive bidding program or as a pay-for for other initiatives under consideration. We are deeply troubled any proposal to cut and/or freeze to the DME fee schedule as that will create significant confusion, frustration, and access problems for Medicare beneficiaries and their healthcare providers. Fourth, we urge Congress and CMS to monitor and review beneficiary experiences and quality of products and services as it moves forward with the competitive bidding program. Experiences from the first round will help secure beneficiaries' interest and enhance the program as CMS moves forward. Finally, we are very concerned that beneficiaries in the competitive bidding areas may mistakenly believe that they are required to utilize a mail-order pharmacy to obtain their diabetic products and services. Thus, we urge Congress to require that CMS involve pharmacists and other providers in creating patient communication materials to ensure that beneficiaries are properly educated about the program.

State-licensed pharmacies should be exempt from the accreditation requirement. The MMA requires DMEPOS suppliers to be accredited to sell covered items to Medicare patients and to participate in the competitive bidding program.[2] The goal of this requirement is to reduce fraud, waste and abuse in the Medicare program. While we agree with CMS on the importance of eliminating fraud, waste and abuse from the Medicare program, we do not believe that requiring accreditation of state-

[1] HealthPolicy R&D, Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community-Based Retail Pharmacies and Blood Glucose Monitoring, Washington, DC, January 2006.

[2] CMS has announced that all suppliers must be accredited by September 30, 2009 to maintain billing privileges under Medicare Part B. Those participating in the competitive bidding program are required to be accredited even sooner.

licensed pharmacies will accomplish this goal. CMS has at its disposal a variety of tools to ensure provider integrity in the Medicare program, which CMS could pursue instead of the onerous accreditation requirement. Accreditation of state-licensed pharmacies is an unnecessary requirement that could threaten patients' access to DMEPOS supplies from their most accessible health care provider

We are concerned that requiring accreditation of pharmacies could result in reducing the number of pharmacies that are available to supply DMEPOS to Medicare beneficiaries. The costs associated with the accreditation process, which can amount to several thousand dollars and hundreds of man-hours for each pharmacy, creates a tremendous financial barrier for pharmacies that provide DMEPOS items to their patients. Pharmacies already struggle to minimize operational expenses to remain competitive in the marketplace, and are skeptical of the accreditation process because even if they undergo the accreditation process, they have no guarantees that they will ultimately be allowed to participate in the DMEPOS program. Combine this requirement with the proposed reimbursement cuts in Medicaid and other state programs and pharmacies are forced to closely examine their expenses.

Accreditation of state-licensed pharmacies is unnecessary due to the comprehensive licensure requirements for pharmacies and pharmacists. Pharmacies are licensed by the board of pharmacy of their respective states to provide services to patients. As part of their licensing process, pharmacies submit to rigorous requirements for their operations and compliance with Federal and state laws. Further, state pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with appropriate laws and regulation. Today's pharmacists are highly educated, licensed experts in the use of medications and medical devices who advise patients and health care providers. These pharmacists are ideally situated to provide Medicare patients using diabetic supplies and other DME items with appropriate counseling and information on the proper use of these items. These qualifications clearly distinguish pharmacies and pharmacists from other unlicensed and unregulated suppliers.

While we believe that accreditation should not be required of pharmacies, we understand the mandate on CMS to implement the accreditation requirement under Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. Nevertheless, CMS' recent implementation of the accreditation requirement through different deadline dates for suppliers with less than 25 locations has resulted in inequitable and unfair treatment of smaller suppliers. On December 19, 2007, CMS announced that existing DMEPOS suppliers enrolled in the Medicare program must obtain and submit an approved accreditation to the National Supplier Clearinghouse (NSC) by September 30, 2009. New DMEPOS suppliers who are enrolled for the first time before March 1, 2008 must obtain and submit an approved accreditation to the NSC by January 1, 2009. However, new DMEPOS suppliers with less than 25 locations submitting an enrollment application to the NSC on or after March 1, 2008 are required to be accredited prior to submitting their Medicare enrollment application.

The accelerated accreditation requirement for existing chain suppliers with less than 25 locations that open new stores on or after March 1, 2008 is arbitrary and unfair. The tiered accreditation deadline based on number of locations creates differential treatment for suppliers. Because CMS has conditioned the Medicare supplier numbers for new locations of an existing supplier on accreditation of the entire chain, the accelerated accreditation deadline also creates a back-log for accrediting organizations. Although CMS provided additional time, until September 30, 2009, for new and existing locations of chain suppliers that have 25 or more enrolled locations to become accredited, CMS retained the unfair tiered approach for suppliers that do not meet the 25 location threshold. While we appreciate the extension provided to suppliers with 25 or more locations, CMS should treat all *existing* chain suppliers with the same degree of fairness and create a single accreditation deadline.

Recommendation: To reduce the difficulties posed by the accreditation requirement on pharmacy providers and to ensure patients' continued access to DMEPOS items, we urge Congress to specifically exempt state-licensed pharmacies from the accreditation requirement. We also urge Congress to ensure careful oversight of CMS' administration of this and other elements of the DMEPOS program to ensure fair treatment of small providers.

Congress should not allow CMS to expand the competitive bidding program to include diabetic supplies sold at retail or to create national or regional competitive bidding areas for mail-order diabetic supplies.

The DMEPOS competitive bidding program was mandated by the MMA. The program is currently limited to 10 metropolitan statistical areas (MSAs) during the ini-

tial round and includes bidding for ten categories of medical equipment and supplies. CMS has also recently announced the second round of the program, which expands the program to an additional 70 MSAs. While CMS has excluded diabetic supplies sold at retail from both rounds of competitive bidding, we urge Congress to require CMS to continue this exemption in the future.

Currently, Medicare beneficiaries can obtain their diabetic glucose monitors and testing supplies from any retail pharmacy that participates in the Medicare program, allowing beneficiaries to obtain all of their covered equipment, supplies, and prescription drugs for managing their diabetes from the same qualified pharmacist. As mentioned earlier, the majority of older diabetic patients rely on their retail pharmacies for their diabetic supplies. Evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for diabetic patients. Through programs such as the "Asheville Project," the pharmacy setting has been shown to provide a successful platform for initiatives to improve adherence to testing and treatment regimens for patients with diabetes.[3] Other private and public health care programs have also placed the pharmacist in a central role in the management of diabetes and other chronic diseases. It would be ill-advised to risk disrupting these pharmacist-patient relationships while further experience is being gained in the effectiveness of community-based pharmacies in promoting adherence to blood glucose treatment and monitoring regimens.

Unlike other DME supplies, CMS did not evaluate the effects of competitive bidding of diabetic supplies during the competitive bidding demonstration projects. Thus, expansion of the competitive bidding program to diabetic supplies sold at retail pharmacies will create significant confusion and frustration to diabetic patients and their providers. At a time when Medicare is attempting to move away from fragmented care, competitive bidding is likely to interfere with patient access and could adversely affect diabetes management.

Further, the study conducted by HealthPolicy R&D examined issues related to competitive bidding of diabetic products and associated services under Medicare Part B and noted the following:

- Costs to the Medicare program will increase if access to the full range of monitoring options is lost or if the frequent in-person counseling by retail pharmacists is disrupted.
- The complexity of using glucose monitors, particularly for an elderly beneficiary, is a major concern. Pharmacists play an important role in helping beneficiaries select the optimal monitors and in the correct use of such monitors, both in terms of initial instruction and subsequent reinforcement of that instruction over time. Much of the professional support originates from the ongoing relationship between beneficiaries and pharmacists.
- CMS excluded blood glucose monitors and supplies from the DME competitive bidding demonstration project, due, in part, to concerns regarding the complexity of matching glucose monitors with the appropriate testing supplies.
- The competitive bidding program could operate contrary to Medicare's current and future initiatives that are designed to promote adherence to blood glucose regimens and reduce overall costs in managing diabetes.

Although CMS excluded diabetic supplies sold at retail from the first and second rounds of competitive bidding and diabetic supplies sold anywhere from the second round, CMS continues to maintain that it will soon create a national or regional mail-order program for diabetic supplies.

CMS' decision to expand the mail-order program for diabetic products would not be supported by any evidence that mail-order program would ensure quality products and services or guarantees as to patients' access to life-saving diabetic products. As CMS' primary motivation appears to be financial savings, it is quite likely that a winning mail-order supplier may limit access to high quality products and eliminate patients' choice in their diabetes care in order to cover reduced reimbursement under the mail-order competitive bidding program.

Further, CMS has not engaged in any study or evaluation of the impact of a mail-order diabetes program on patients' health outcomes and overall increase in cost to the Medicare program from patients' failure to abide to their prescribed testing regimen. As mentioned earlier, proper match between diabetic test strips and monitor is critical to optimal diabetes management. If patients are unable to access proper diabetes test products or find it difficult to manage their diabetes with low-quality products, they are much more likely to stray from proper testing regimen or stop

[3] Pharmacy Times, The Ashville Project: A Special Report (October, 1998), available at http://www.pharmacytimes.com/files/articlefiles/TheAshevilleProject.pdf (last accessed May 12, 2008).

testing entirely. These behaviors are likely in a program that denies access to retail pharmacies and could harm patients and increase Medicare spending.

Like many other chronic diseases, diabetes has a disproportionate impact on minority and low income patients. These populations are less likely to be able to navigate a competitively bid mail-order market for their diabetes products. As retail pharmacies and providers are selectively forced out of diabetic supplies business through the expansion of the mail-order program, minority and low income populations will find it increasingly difficult to access these products. Expansion of the mail-order program will effectively compel these vulnerable populations to go without proper diabetes management.

As previously stated, the majority of older patients prefer to obtain DME supplies for conditions such as diabetes from their local pharmacist with whom they have an ongoing relationship. The presence of a licensed pharmacist at their community retail pharmacy gives patients the opportunity to discuss the best glucose test monitors for their individual needs and the proper matching of the test strips to the glucose test monitors. This individualized attention is critical to helping increase patient compliance with therapy regimen and improving health outcomes for diabetic patients. The benefit of such interaction should not be taken lightly as it provides a valuable patient care forum for early awareness and treatment of diseases, and translates into substantial savings for the Medicare program. Expansion of the mail-order diabetes program will make it more difficult for Medicare patients to gain access to the community pharmacist they trust creating a likelihood for miscommunications and misunderstandings and eroding the benefits of the pharmacist-patient relationship that has been proven to improve health outcomes and reduce overall health care spending.

Congress should reject proposals to cut and/or freeze the DME fee schedule.

Despite inflation and increased costs in providing DME services, some have proposed that the DME fee schedule be cut or the fee updates remain frozen as an offset for a delay of the competitive bidding program or as a pay-for for other initiatives under consideration. Foremost, Congress should recognize that DME fee schedules have not been updated to reflect the true cost of providing these products and services. We urge Congress to evaluate the administrative costs incurred by providers in the DMEPOS program and require the update of these schedules accordingly. Absent meaningful reforms, a delay of the program funded through cuts to providers will harm Medicare beneficiaries and small businesses.

CMS excluded diabetic products sold at retail pharmacies from the first two rounds of the Medicare competitive bidding program in part because of the unique nature of this disease and the potential harm to beneficiaries. Management of diabetes requires very careful monitoring of blood glucose and pharmacists serve in a team comprising of doctors, patients and diabetes educators to help patients properly manage the disease. Medicare beneficiaries understand that interaction with a pharmacist is critical in proper diabetes management, and therefore a vast majority of beneficiaries rely on their community pharmacies for their diabetic products and services. Therefore, we urge Congress to preserve these relationships by ensuring patients have access to their local pharmacies and reject any proposal that would cut and/or freeze DME fee schedule updates.

CMS should monitor and review beneficiary experiences and quality of products and services.

NACDS is concerned that CMS' focus on reducing costs of the DMEPOS program may force many suppliers to substitute lower quality products and services to cover reduced reimbursement under the competitive bidding model. We urge Congress to require that CMS evaluate experiences from the implementation of the first round of the program as it moves forward. In particular, CMS should carefully monitor and evaluate whether contract suppliers are able to satisfy demand. CMS should also be required to evaluate the impact of the program on beneficiaries' access to high quality products and services. All results from CMS' evaluation or surveys should be made available to the public.

We also urge Congress to require the Government Accountability Office (GAO) to conduct a thorough analysis of beneficiary experiences in the program. These analyses should include, among other things, impact on health outcomes and increased costs to the Medicare program from missed therapies due to beneficiaries' inability to access products or navigate a competitive bidding program. We believe that a thorough analysis of round one is necessary in advance of implementing further rounds of the program.

CMS should involve pharmacists and other providers in drafting patient communication materials.

With less than two months remaining before first round mail-order diabetic supplies contracts go into effect in the 10 MSAs, CMS has yet to embark upon an effec-

tive patient outreach program. As the first round becomes effective on July 1, 2008, patients are likely to be confused about where they can obtain their DMEPOS products and services.

In particular, diabetic patients in the 10 MSAs may mistakenly believe that they are required to utilize a mail-order facility for their diabetic supplies. CMS should be required to clearly state on any beneficiary communication material that patients in the 10 MSAs may continue to utilize their local pharmacies for their diabetic test supplies. As mentioned earlier, interaction with licensed pharmacists at retail pharmacies provides benefits that are not achievable when patients receive their diabetic products through mail-order. Congress should require CMS to work with pharmacists and other healthcare providers in developing proper communication materials to ensure that patients are not steered away from retail pharmacies, depriving them of professional counseling of their pharmacists.

CONCLUSION

NACDS appreciates the opportunity to work with Congress to ensure that our seniors have access to the best healthcare products and services. We thank you for this opportunity.

Statement of National Coalition for Assistive and Rehab Technology

The National Coalition for Assistive and Rehab Technology (NCART) appreciates the opportunity to submit the following written comments regarding Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS) Competitive Bidding Program. NCART is a coalition of suppliers and manufacturers of assistive and rehab technologies. The coalition's mission is to ensure proper and appropriate access to rehab and assistive technologies, which CMS classifies under durable medical equipment (DME). We sincerely appreciate the consideration of the committee and its concerns regarding the implementation of the competitive bidding program.

Throughout the planning through today we have been advocating for the exemption of complex rehab products from Competitive Bidding. Complex rehab products are medically necessary adaptive seating, positioning, and mobility devices that are evaluated, fitted, configured, adjusted, or programmed to meet the specific and unique needs of an individual with a primary diagnosis resulting from injury or trauma or which is neuromuscular in nature. A good example of these products is the type of power wheelchair and seating system used by the late Christopher Reeve These represent a very small subset of the Medicare expenditures yet have a major impact on Medicare beneficiaries who are severely disabled.

The Program Advisory and Oversight Committee (PAOC) advised CMS to exempt complex rehab from competitive bidding due to the fact that none of the demonstration projects included customized items. Because of this, CMS lacked the necessary knowledge regarding the impact to consumers. In addition, the PAOC believed that competitively bidding complex rehab devices would produce insufficient savings and would negatively impact the clinical outcomes of beneficiaries. NCART as well as clinical groups and consumer advocacy groups have advised CMS that complex rehab technologies are not appropriate for competitive bidding and our position on this has not wavered. However, this advice was generally ignored and many items classified as complex rehab are included in Round 1. Many groups involved in protecting access to this technology for Medicare beneficiaries with disabilities are involved in on-going efforts to exempt these items from the competitive bidding program.

The exemption of complex rehab has a solid base of support. Major disability advocacy groups have held meetings with Congress and provided written support. These include the Muscular Dystrophy Association, the ALS Association, and the National Council for Independent Living. In addition, legislation has been introduced in the House and the Senate to provide for this exemption, H.R. 2231 and S. 2931.

Complex Rehab Should be Exempt

There are a variety of essential reasons that complex rehab technology should be exempt from the competitive bidding program:

The original Legislation specifically exempted custom orthotic devices because they require individual evaluation and fitting. The items falling under complex rehab meet this same definition and we believe Congress did not intend that these types of items be included.

Moreover, these items are a very small subset of the Medicare DME expenditure, for example less than 10% of the total dollar spent for power mobility, yet they are critically necessary for those Medicare beneficiaries with diagnoses such as spinal cord injury, traumatic brain injury, cerebral palsy, muscular dystrophy, spinal muscular atrophy, spina bifida, amyotrophic lateral sclerosis, and multiple sclerosis.

Decreased access to individually prescribed devices will lead to poor clinical outcomes—This level of customization does not lend itself to competitive bidding. Current HCPCS codes do not adequately define or distinguish technologies. Devices that vary in intended use, clinical application, technology and price are amalgamated into single HCPCS codes with a single payment amount. In many cases the current Medicare fee schedule does not allow access to the full range of technologies within a code; the reduced single payment amount will further block access to critical technologies. Items within a single HCPCS code are not interchangeable and therefore will not meet the identified medical needs of the Medicare beneficiary. Complex rehab devices are individually fit, measured, adjusted, programmed and otherwise modified to meet the specific needs of an individual.

Insufficient savings—Complex power mobility is an extremely small portion of power mobility utilization, less than 10 percent of the power mobility benefit, according to a CMS contractor. Furthermore, an analysis completed by The Moran Company estimated exempting complex rehab from competitive bidding would only reduce savings by $46 Million over five (5) years.

Implementation Issues Providing Further Evidence of the Need to Exempt Complex Rehab from the Competitive Bidding Program:

Inexperienced suppliers are allowed to bid—Suppliers that were accredited prior to the release of the Quality Standards are considered to be accredited and compliant with the quality standards even though the criterion used to survey these suppliers at the time does not meet the current standards. As a result, inexperienced suppliers, suppliers who have never provided complex technology and who do not employ knowledgeable or credentialed staff are being allowed to contract under competitive bidding. This will impact the clinical outcome of Medicare beneficiaries. In addition, these suppliers do not have the needed knowledge of the HCPCS codes and the range of technology represented by the codes to submit a reasonable bid.

Suppliers are not required to have a physical location—The cumulative effect of Medicare policy and regulation is that suppliers are not required to have a physical location in a service area or CBA, they are not required to have a technical support staff or credentialed rehab technology supplier on their direct payroll. The ability to gain market share with no direct costs; the ability to only incur cost associated with the provision of a product certainly allows suppliers to reduce their over-head and therefore submit a lower bid price. However, the impact to individuals with severe disabilities will be reduced local presence and reduced access to the critical services associated with complex rehab technologies.

Supplier's express two basic reasons for bidding in an area they do not currently have a presence:

- The opportunity to move into a new market and rapidly gain market share. With current market leaders potentially eliminated combined with the mandatory requirement for beneficiaries to receive product from contracted suppliers, there is a strong opportunity to gain market share with no financial investment. However, these suppliers lack an understanding of the market and the cost to properly service the market.
- Opportunity to "practice" the bid process. This allows suppliers to be prepared to submit a bid in subsequent bidding rounds. These bids offered an opportunity for these bidders to understand the bid evaluation and to understand how to improve the chance of winning contracts in their market. They did not have to worry about the impact of their bid amount on the ultimate payment.

Suppliers are not required to provide service and repair—Because contract suppliers knew they would not be required to service and repair the devices on which they bid, they had an incentive to lower the bid on these parts to strengthen their overall bid. However, the bid did establish the single payment amount that will apply to all suppliers. Noncontract suppliers will be unable to ensure ongoing access to service and repairs because the contracted bid price is too low.

Claimed Savings is Erroneous

- CMS used 2005 utilization data to establish item weighting—This did not allow a distinction between standard and complex power mobility bases and did not identify accessory utilization by category. As a result, substantial errors were made in the savings calculation:

- 2006 coverage and coding changes established a "Basic Equipment Package"—revised code-set and coverage policies were implemented in November 2006. The coding changes also added a "Basic Equipment Package". This package contains many items which had been highly utilized with standard power mobility. This package is included in the base fee schedule for the power wheelchair and the items are no longer separately billable. As a result, there are no additional savings for these items; therefore, they should not be included in the savings calculation.
- Rarely used or non-covered items included in savings calculation—CMS was not able to distinguish accessory use by category (standard v complex rehab). As a result accessories were included in the complex rehab category bid which are not billed with these complex bases. An example is U1 batteries, with an item weighting of 0.128529214, were included in the complex rehab bid. These batteries are not used in complex rehab power mobility bases due to the fact that they do not provide enough power to meet the performance requirements of the code-set. These smaller batteries are routinely utilized in the smaller bases characteristic of standard power mobility. This item and others like it should not be included in the calculation of savings.

Conclusion

It is critical that complex rehab devices be exempted. The strong support of the disability groups such as the Muscular Dystrophy Association, the ALS Association and the National Council for Independent Living.provide solid evidence that Medicare beneficiaries are very concerned about the negative impact that is sure to come. The legislation introduced in Congress will provide for this relief and protection for the Medicare beneficiaries with the most severe disabilities. We urge members of the Committee and all members of congress to support the passage of HR 2231 and S 2931 at the first opportunity.

Statement of National Competitive Bidding

National Competitive Bidding is a way for the Centers for Medicare and Medicaid Services (CMS) to reduce the number of providers who will be able to deliver and bill for services which are patient preferred and provided in the home setting.

CMS uses Fraud and Abuse as the initiative for reducing the number of providers. What is wrong with this? Let us ask you to have CMS address the following issues:

- First and foremost over the last 15 years HCFA and now CMS has implemented more stringent requirements to become a provider of durable medical equipment. One needs to ask; if there is fraud and abuse who is overseeing the CMS contractors who implement the requirements?
- CMS has the authority to reduce prices through inherent reasonableness. Why reduce the number of providers at an expense yet to be determined to implement this program?
- Services of Durable Medical Equipment Providers are not reimbursed, but they are provided. In order to continue those services providers must do business locally. The Competitive Bidding Program has few providers in a large geographic area and although the winners are permitted to subcontract, who will oversee the quality of services delivered? The contracted provider must guarantee quality. If CMS cannot control their own perceived fraud and abuse now, how will they oversee multi-tiered services?
- Accreditation is mandatory at an expense to the provider. In essence CMS has implemented a program where someone will see to it that standards are met, at the provider's expense. Most providers were voluntarily accredited for years and those who are scrambling to do it now are providing minimum services. Many will no longer participate in the program leaving the beneficiary with limited choice. Has that been considered?
- Gasoline prices were not what they are today when the initial bids were submitted. This will certainly impact the service component that is not reimbursed, who will oversee that deliveries are coordinated and timely?
- CMS pronounces that Beneficiaries will save since their co-pay will also be reduced when reimbursement is reduced. The majority of Beneficiaries have supplemental insurance or Medicaid. It is those on the border of being eligible for Medicaid with an out of pocket expense. Will CMS, or Congress ask those supplemental carriers to reduce their premiums, because it is they who benefit from a reduction in co-pay amounts? The beneficiary saves nothing.

- Limiting the number of providers just limits the beneficiary's access to local services. Many are accustomed to going to the provider of their choice and have developed a relationship with them. Has that been considered?
- Competitive Bidding could and will result in the beneficiary receiving services from multiple providers. How will they cope with all of that? Did anyone consider that?
- Referral sources handling the continuum of care in the home will have to juggle multiple calls to multiple providers to coordinate this care. Did anyone consider that?

While the savings that CMS anticipates are not guaranteed and are speculative at best; services to beneficiaries will be negatively impacted. There is no doubt that will happen. The beneficiary is not considered at all in this obsession to reduce costs at the expense of the providers that are relied upon by many. This is especially true when CMS could reduce reimbursement without the added cost of overseeing yet another contractor and this program.

If the winning provider fails, what does the beneficiary do then? By the time CMS finds out there is a problem you can be guaranteed there will not be another provider so eager take over, if there is one available at all.

New Jersey is listed in two MSAs in Round Two, but we have yet to receive the area of the state. Is it northern NJ, or all of NJ? The CMS Contractor states they do not have the information. Will a provider be expected to deliver services from Montauk Point, NY to Cape May, NJ? Or is it Allentown, PA to Camden, NJ? We are listed with PA locations and NY locations. How could this crucial information not be available?

With the questions that remain unanswered, we believe that the Congressional Oversight Committee should ask specific questions of CMS detailing its own oversight of their own contractors. Ask yourself if there is fraud and abuse, who pays the claim, who does an on-sight inspection of the provider's location, who writes the rules and policies, how does CMS measure the quality of service these contractors provide? Maybe we should start there before we reduce reimbursement, access and the quality of care beneficiaries currently require to remain in their homes. The alternative is institutional care, at a far greater cost to the program, the patient's family, and ultimately the beneficiary that CMS tells us they are protecting. This is a systematic dismantling of the program under the guise of reducing fraud and abuse and achieving costs savings.

Statement of National Home Oxygen Patients Association

The National Home Oxygen Patients Association (NHOPA) welcomes the opportunity to comment on competitive bidding as it affects our members, users of home oxygen therapy.

Our comments focus on what we have seen so far as implemented by the Centers for Medicare and Medicaid Services (CMS), what we have not seen, and what we anticipate will occur July 1st and thereafter based on competitive bidding for home oxygen therapy.

First and foremost, we must strongly emphasize that bidding for oxygen and related services is, by definition, a flawed process because the current payment methodology for home oxygen is seriously flawed. Competitive bidding for oxygen will likely exacerbate the situation, not improve it. Under current statute, payment for new technologies such as lightweight liquid systems, portable oxygen concentrators, and transfilling systems is based on the pricing for stationary concentrators. Simply stated, the statute that ties the payment of devices that today cost approximately $2500-$3500 to devices that cost $450 is irreparably flawed. Access to these lightweight technologies is critical to the oxygen user population, and any effort to reduce payment for these devices will unquestionably put a greater strain on access to these technologies.

For example, in non competitive bidding areas, stationary concentrators trigger a $199 payment, with an "add-on" of either $31 or $51 for the newer technologies. The former costs a supplier around $450, while the latter costs $2500-$3500. The very appropriate downward pressure on payment for stationary concentrators has the unfortunate effect of reducing payment for other devices, making access to them even more problematic.

Secondly, we were quite chagrined by CMS' claim at the public hearing on May 6th indicating that its advisory committee, the PAOC, served as an important liaison for input from the consumer community. Oxygen is far and away the largest

single component of the durable medical equipment benefit, yet CMS did not include either an oxygen user or a pulmonary physician as part of its advisory board. Our views have, bluntly, been ignored by CMS.

Additionally, in 2007 we were approached by CMS contractor Abt Associates to assist in the development of a questionnaire/survey instrument to help assess the impact of competitive bidding, yet Abt ended that process before completion. It is very difficult to believe that there will be an accurate and appropriate assessment of competitive bidding unless there is an accurate picture of access and quality **prior** to competitive bidding in the 10 MSAs where competitive bidding is slated to begin July 1st, 2008. Simply, one cannot assess impact unless one has a fair picture of the provision of oxygen and related services prior to July 1st.

With competitive bidding less than 8 weeks away, to our knowledge there has been no direct outreach to oxygen users in any affected MSA. If we understand the program correctly, a beneficiary whose supplier is not a winning bidder and chooses not to accept the winning bid under the "grandfather" provisions, will be required to find a new supplier. That new supplier is unlikely to provide the identical oxygen system, and we understand and appreciate that some educational information will need to be provided regarding new stationary systems, new portable systems, and new oxygen conserving devices. NHOPA has already begun that effort, but we see no movement by CMS to educate beneficiaries.

The beneficiary who must find a new supplier will likely have a chaotic July 1st as new equipment arrives and old equipment disappears. While a seamless process is possible, we are not exactly confident that such a transition will occur. Once the old supplier pulls his equipment from the home, unless the new equipment is present and ready for use, there could be significant clinical risk.

In terms of replacement equipment by the new supplier, CMS' own pilot study of competitive bidding/oxygen usage in Polk County, FL and San Antonio, TX saw a reduction of 30% in access to lightweight oxygen systems. CMS has never pursued our concerns regarding that matter, and implementation of this program absent such program changes will unquestionably trigger similar, dramatic access issues. There is already some evidence that access to liquid oxygen systems in competitive bidding areas may be problematic, and this is of major concern to NHOPA.

There has been important discussion within the oxygen community regarding a slow down of Phase Two of competitive bidding. We believe that it is appropriate to implement Phase Two once there has been a reasonable and accurate assessment of the impact of Phase One of competitive bidding AND time for CMS to adjust the program based upon that assessment. We find it hard to believe that such an assessment could occur in time for a January 1, 2009 commencement date. We also believe that there are ways to achieve ample savings within the Medicare home oxygen therapy benefit that would, in the aggregate, save Medicare, and the Congress/taxpayers, millions. By establishment of a payment system that bases payment on a patient's clinical need as determined by the prescribing physician rather than the supplier, and basing those payments to align on the cost associated with acquisition, delivery, etc., significant savings could be achieved. It would take, however, aggressive action by the Congress to implement such changes.

Statement of Pennsylvania Association of Medical Suppliers, Mechanicsburg, PA 17050

Introduction

The Pennsylvania Association of Medical Suppliers (PAMS) is America's oldest state advocacy organization representing the interests of home medical equipment (HME) providers. Our membership is comprised of companies that are overwhelmingly small and independently owned. Our members are in the business of helping people with serious health conditions live comfortable lives in their own homes. In doing this, our members help the health system save substantial dollars.

We are able to introduce savings to an ever-more-expensive health system because homecare is a low-cost alternative to some of the most expensive forms of health care, such as long-term care and hospitalization.

Homecare is Cost Effective

In Pennsylvania alone, the cost to the state's Medical Assistance (Medicaid) system to place a single individual in a long-term care facility runs an average of about $56,000 per year. In comparison, it costs about $23,000 per year to give that person the same level of care in their own homes.

But the savings potential from HME providers doesn't end as an alternative to long-term care facilities. People with long-term respiratory problems, such as COPD, can receive home treatment for an entire year for less than the cost of a single day's visit to the hospital. That's an average of about $6.65 per day for in-home oxygen care vs. a national average in excess of $4,600 per day for a hospital stay. Our home infusion therapy providers offer a variety of life-sustaining intravenous medications, including chemotherapy, which are far more cost-effective than the alternatives of in-patient or out-patient treatments. The average cost per day of home therapy was $122, compared to $798 in the hospital and $541 in a skilled nursing facility setting.

PAMS would respectfully urge you to remember these numbers as Congress searches for ways to find savings in the Medicare and Medicaid systems. Our industry, in conjunction with home healthcare professionals, can provide individual, in-home care for roughly 40 percent of the cost of long-term institutionalization. We challenge you to find another healthcare sector that is capable of making a similar claim. And who wouldn't want to remain in their own home given the choice?

Competitive Bidding

The National Competitive Bidding (NCB) program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) as designed by CMS is a fatally flawed and highly unusual version of government competitive bidding programs. It is a program that has managed to disqualify more than six out of ten bidders for technical reasons not related to pricing. The fact that these hearings are even necessary should serve as fair warning that CMS managed to do something terribly wrong to an exercise that is commonplace at virtually every level of government.

We all know that competitive bidding is normally a simple, straight-forward and cost effective process. It is utilized by local governments to ensure that trash is collected reliably and at the lowest cost possible. It is used by state governments for cost-effective highway construction and maintenance projects. Our nation's military preparedness is largely dependent on a series of defense contracts supplying everything from meals and boots to fighter jets and aircraft carriers.

Why is it that these government-run competitive bidding projects seem to work flawlessly and yet the CMS DMEPOS competitive bidding program has been subject to problems, complaints and criticisms since its inception?

The problems with the CMS bidding process are numerous, but we can point to three major problems that differentiate it from successful competitive bidding programs and form the foundation for our claim that the program is fundamentally flawed—that is, that the program is incapable of operating successfully and that it will jeopardize patient care if not delayed immediately and thoroughly overhauled.

The three major problems that create the fundamental flaws in the CMS bidding process are as follows:

- It is anti-competitive;
- It misunderstands the nature of successful bidding programs; and
- It is conducted at the retail level.

It is anti-competitive.

The first major flaw with the CMS bidding process is that it was designed to eliminate competition rather than promote it. In the Pittsburgh MSA, for example, CMS reported the presence of 289 DME providers. In Round One, CMS reported that it offered contracts to 52 bidders. This means that 82 percent of the competitors in this market have been frozen out of competing for Medicare business. More importantly, it means that Medicare beneficiaries have lost eight out of ten choices for finding the best and most convenient DME suppliers to serve their in-home medical needs.

Eliminating community-based competition on an order of this magnitude makes very little sense. Policy makers like the idea of competitive bidding because experience has taught us that competition is a good thing—especially for consumers. But how can we call a program "competitive" when one of its chief purposes is to eliminate competitors from the marketplace?

According to the report The Impact of Competitive Bidding on the Market for DME (copy attached) by Robert Morris University economics professors Brian O'Roark, PhD and Stephen Foreman, PhD, JD, MPA, "interference with competitive markets inevitably leads to higher, not lower, prices. Indeed, the customer base for medical equipment and supplies is expected to grow dramatically during the next 20 years. Artificially restricting the market now will lead to substantial market failure in 10 to 20 years."

Drs. O'Roark and Foreman note that there are many reasons why competition is desirable to consumers and the overall public welfare: "Prices tend to be lower and

consumer options greater." The study concludes that there may be "a short-run advantage to CMS if successful bidders are willing to cut price (or pay a premium) to gain market power, and it may be easier to regulate fewer firms. However, in the long-run, the bidding scheme will have traded a competitive market for a government-mandated concentrated market. As a result, we will have traded small, short-run benefits for major, long-run problems—poor public policy indeed."

The study further points out that the selective capture of such major, competitive and established markets runs counter to the most fundamental standards of fairness governing the normal operation of U.S. markets. "United States antitrust laws promote and maintain competition in the marketplace. Artificial limits on competition are so serious that collusion to limit competition is a criminal offense and may result in the award of treble damages."

The CMS bidding program blatantly manipulates the market for DME, eliminates a large number of well established and reputable DME providers, and further erects an impenetrable barrier to new entries into the market. If privately owned companies were to attempt this level of market manipulation, it would be illegal because it would be anti-competitive.

Real competition keeps prices low, gives consumers choices, and holds competitors accountable for the quality of their products and services. Open markets and competition deliver lower prices and better service. The current competitive market for home medical equipment works well for consumers and patients and should not be traded for a government-mandated scheme that compromises patient care.

It misunderstands the nature of successful bidding programs.

The CMS bidding process is radically different from successful government competitive bidding programs in its incredibly broad scope. Normal competitive bidding programs tend to deal with a single and well defined product or service. The DMEPOS bidding program, by comparison, deals with hundreds of widely varying products that were thrown together into a stew in order to arrive at what CMS refers to as a "composite bid" price for each bid category.

In a peer-reviewed economic study that appeared in the January 2008 issue of prestigious Southern Economic Journal (copy attached), researchers studying the DMEPOS competitive bidding demonstration projects in Polk County, FL and San Antonio, TX said that the CMS program design demonstrated "a fundamental misunderstanding of auctions." In other words, CMS doesn't know how to run a competitive bidding program (auction).

The study said that it is a "common misconception is that the desirable properties of single-unit auctions extend to multi-unit auctions. However, recent theoretical breakthroughs show that there are actually very few multi-unit auctions that possess the famous efficiency and revenue-generating properties of single-unit auctions. In fact, the majority of multi-unit auctions are inefficient and can deliver vastly different expected outcomes."

It should come as no surprise to the authors of the study that the CMS bidding program for Round One experienced problems at virtually every level and at every stage. The only thing that should surprise anyone at this point is CMS's stubborn insistence on pushing through such a thoroughly flawed and discredited program. Even the so-called "successful" results invite serious skepticism from anyone familiar with this industry. But CMS has not exhibited any curiosity as to how it is that the smallest companies with lesser competitive advantages were able to outbid the largest companies with superior competitive advantages and the greatest incentive to capture market share by "purchasing the franchise" for the markets bid in the form of artificially low prices. Although this result may have been an undesirable outcome, it at least would have been an economically predictable and understandable outcome. The actual outcome of the DMEPOS bidding process was neither predictable nor understandable from an economic standpoint.

In addition to the complexities created by the "multiple units" that were put out to bid in the CMS DEMPOS bidding program, bidders had very little guidance on how many units were to be bid. It is standard operating procedure for such bids to provide this basic detail so that bidders can determine optimal pricing.

When a local government bids trash collection, the number of households and the square mileage of the municipality are known to bidders. When a state highway department bids a roadway construction project, the length of roadway, number of lanes and materials to be used are known quantities. When the Defense Department bids fighter jets, the design specifications and number of aircraft to be manufactured are known. Again, these are all examples of successful government bidding programs.

By contrast, the CMS program, in addition to the "multiple units" problem, provided wide latitude on quality specifications and no direction on the number of units

to be supplied. The latitude on quality standards creates an incentive to use low-cost, foreign-made medical equipment from foreign manufacturers, such as China, where quality control issues in other areas have been widely reported as problematic. The lack of specificity on the number of units to be supplied created the untenable situation where vendors were left to literally guess at how many of any given product they actually would be supplying if successful. The fact that anyone bid at all is an indication of the extreme duress that the world's largest purchaser of medical equipment and supplies placed on the overwhelmingly small community-based DME suppliers who populate this industry.

To make matters worse, CMS and its Competitive Bidding Implementation Contractor (CBIC) created the impression that bids would be granted in intervals "not to exceed 20 percent." Most bidders and other industry observers assumed that contracts were to be assigned to five or six providers in each product category. It came as a surprise to most to learn that contract awards were offered to 20, 30 or more bidders in different MSAs for different product categories. It is a very big difference for a bidder to seek product pricing on the assumption that someone would be supplying 20 percent of a market only to be offered five percent of that market. This is a very significant flaw for a competitive bidding program.

The CMS bidding process was both unusual and unprecedented in its scope, sheer size and complexity. This created confusion for most at virtually every stage of the process.

It is conducted at the retail level.

Finally, it is highly unusual for a national product procurement process of this magnitude to be conducted at the local retail level. Because of the enormous purchasing power of the Federal Government, its competitive purchasing programs are typically conducted among a relative handful of very large national competitors.

As has already been noted, retail providers of medical equipment and supplies are overwhelmingly small, independently owned and locally operated. Such small retailers do not control the costs of production or wholesale distribution. Our members are at the very end of the distribution chain. They deliver these products and services and make sure that patients are properly trained in the safe and proper use of the equipment and further ensure that the equipment is properly maintained. DME providers are in a very poor position to guarantee product pricing for three years since they do not establish product pricing.

It is no more appropriate to ask local DME retailers to bid competitively for Medicare business than it would be to ask local physicians or dentists. Medicare beneficiaries who utilize such medical equipment and supplies are typically elderly, disabled or both. They look for DME providers who are competent, reliable and conveniently located—just as most would look for a physician. Eliminating conveniently located providers, while simultaneously eliminating market pressures to provide quality care, is simply wrong-headed.

Federal bidding programs are normally structured to protect small business interests from both larger competitors and the massive purchasing power of the Federal Government. CMS is quick to point out that 64 percent of its DMEPOS contract offers went to small providers. This number is terribly misleading. A large percentage of a small number of winning bidders simply covers up the fact that an even higher percentage of the overwhelming majority of small retail operations serving communities and Medicare beneficiaries throughout the country are being placed at the risk of financial failure as a result of this program. As already mentioned, 82 percent of DME providers in the Pittsburgh MSA will be excluded from participating in the Medicare program as a result of this program.

It is simply wrong for CMS to run roughshod over so many small businesses as a matter of administrative ease—the only possible reason to seek to eliminate an established and reliable network of retail providers of these important medical goods and services. This is a network that came into existence because it provides ease of access and quality care to Medicare beneficiaries, no different than the network of local and independent physicians and dentists throughout the country.

Everyone understands the need to save money in the Medicare program. This is an inappropriate and unworkable means toward that end.

Program Viability

Pennsylvania is home to the Pittsburgh CBA in Round One of NCB and the Scranton/Wilkes-Barre and Allentown/Bethlehem/Easton CBAs in Round Two. As such, PAMS is greatly concerned about the impact that the CMS bidding program will have on our Medicare beneficiaries and the DME providers who serve their medical needs.

At best, we believe that the program savings reported by CMS as a result of Round One bidding are questionable. CMS, at the urging of the Small Business Administration, once felt certain that it was necessary to carve out a guarantee that 30 percent of contract offers would go to smaller providers earning less than $3.5 million in gross annual sales. The assumption was clear: smaller providers could not compete against the overwhelming advantages of the large national and regional providers. No one disputed that assumption. Yet, somehow, the smallest suppliers managed to not only survive the bidding process, but to substantially dominate it, winning 64 percent of Round One contract offers according to CMS.

How did that happen? One theory holds that smaller suppliers were fearful that larger suppliers had a competitive advantage in the bidding system and didn't trust CMS to recognize them as part of the program small business set-aside. The result was that smaller suppliers felt compelled to remain viable by bidding at levels that were unsustainable. This theory further assumes that bids from larger suppliers would reflect more-accurate pricing and would serve as a moderating influence on the final composite bid price.

What, in fact, is likely to have occurred based on the number of small suppliers who "won" contracts, is that the small suppliers met the CMS capacity requirements and larger supplier bids were not needed to meet unspecified capacity requirements. The RMU study mentioned previously cited the potential for such unfortunate "favorable" outcomes. It is known in economic literature as the "winner's curse." In this case, the so-called *winner's curse* has led to pricing that is not likely to be sustainable over the longer term.

Industry observers are highly skeptical of the final bid awards and this Committee should be concerned about the viability of this important segment of the Medicare program. According to Drs. O'Roark and Foreman, "Often the successful bidder will have the low bid because it has made mistakes in estimating its future costs at the time of bidding. In this case the firms that have won the bids have offered to sell the products at inordinately low prices," perhaps lower than affordable or sustainable—especially in light of skyrocketing gas prices and current economic conditions. Consider that gasoline prices have risen by more than 65 percent in the nine months since bids were originally submitted to CMS in September of 2007. Considering that home delivery is a critical component of this business, it should stand to reason that something has to give.

Thus, "winning" firms must cut costs. "The most likely targets for cost reductions," according to the RMU study, "are customer service and product quality. Such reductions are made easier because the NCB program has reduced the number of competitors in each market and each of those competitors will be facing the identical cash flow problems. "Consumers will have few alternatives available, so poor service is likely to become commonplace."

In short, the service provided to Medicare beneficiaries will probably fall victim to the proposed DME bidding scheme—as will future prices paid by CMS and the public. This is simply the law of unintended consequences at work.

Moreover, the argument that the pricing levels established through bidding are indicative of market pricing is misleading. The purchase of a commodity through an online internet vendor, for example, is void of compliance with any healthcare insurance or accreditation system. It is a cash commodity transaction without any regulatory obstacles and does not account for any service costs such as 24/7 on-call service, facility overhead costs, credentialed personnel, or the significant costs associated with billing Medicare. Therefore, it is inappropriate to make any comparison to the internet pricing and Medicare allowables.

Also, as we have previously noted, lesser quality items, reduced and disrupted services, access problems and beneficiary confusion will lead to additional program costs in the form of hospitals stays, physician visits and an increase in 9–1-1 emergency calls in the absence of the high quality, around-the-clock service provided by most HME providers operating in the current competitive environment. None of these factors has ever been identified by CMS in its presentation of savings that can be achieved through bidding.

PAMS strongly urges this committee and this Congress to immediately impose a significant delay the implementation of this program, which otherwise will be implemented on July 1, 2008. The wide range of problems and questions about the program must be independently evaluated, and an alternative process to determine payment rates for home medical equipment must be explored.

Homecare is part of the solution for Medicare. It is not the problem.

Statement of Robert Brant

To addresses and raise the specific issues of the hundreds of companies affected by the turmoil of the bidding process, and to speak on behalf of the millions of patients whose care will be significantly negatively affected by the roll out of this process, We formally request a representative of the Accredited Medical Equipment Providers of America, Inc. (AMEPA) speak at the Hearing HL–24.

This ongoing bid process was begun in 10 MSA and is slated to be rolled out across the nation over the next two years. The initial process has been a fiasco, there was a serious manipulation of applications' rules after a majority of applications were submitted, REGLFEX policies (though required by Federal law) were rejected, and 63 percent of the applicants were erroneously disqualified with no ability the appeal. Senators, Congressmen and senior legislative staff have identified these problems as "gross negligence" by the Center for Medicare and Medicare Services (CMS). The results of which will be a limiting of access by patients to much needed care, unqualified companies will be providing incomplete services and major metropolitan areas will be grossly underserved during times of emergency. In addition 17,000 to 21,000 gainfully employed Americans will lose their jobs.

AMEPA is an organization founded by medical equipment providers affected in the initial 10 MSA's and is now gaining strength in the next 70 MSA's soon to be subject to this flawed process. We are working with 100's of providers who were disqualified erroneously or have failed to win a bid due to the poor implementation of the program by the Competitive Bidding Implementation Contractor, Palmetto GBA, LLC. They have joined AMEPA in the hope to communicate with Congress on this issue.

We have included two attachments; the information below is related to them and to new developments regarding the competitive bidding process. Please review:

- A provider from Texas, applied for and won the Oxygen Category in 9 out of the 10 Metropolitan Statistical Areas (MSA's). This bid winner has never provided the item before outside of their own area. According to Florida State records, the company is not licensed by Florida's Agency for Healthcare Administration as a Home Medical Equipment Provider. The bid winner does not have a License to deliver Oxygen from the State's Department of Health either. They are not licensed.
- The first line in the Rules For Bid (RFB) states that "All suppliers must—meet any local or state licensure requirements, if any, for the item being bid". Clearly this bid winner did not meet the requirements for the bid he won in Miami and Orlando. We believe that it was not the intent of Congress to allow something like this to happen.
- According to the Rules For Bid (RFB) companies were required to prove that they could cover the complete geographical area of the MSA prior to bidding. The attachment proves this Bid Winner did not have any subcontract agreements in place before they bid, as they are currently attempting to find existing providers to do their work.
- This bid winner and other out of state bid winners should clearly not have won the bid for oxygen and CPAP. Their bid should have been disqualified for not meeting proper licensure requirements. If their bid was properly disqualified, their bid price would have been removed from the Composite Bid, and all pricing would be affected, and other bid losers should take their place.
- Another attachment is from a bid winner in Miami and Orlando. This winner has changed their policy and as of April 1, 2008 (not July 1, 2008) they are refusing to deliver a commode or other bath safety products unless the order accompanies Oxygen or another rented item. Providers currently compete in the market by providing equipment at a low margin in order to keep the referral source happy. Now the bid winner does not have to compete for business and is refusing to provide these Medicare covered items which are not subject to the bid as they are considered inexpensive. If the Bid winner will not provide these bath safety products then who will provide them?
- This proves that the program will limit the patient's access to care. If the patient cannot get their prescribed medically necessary equipment from a bid winner they are unlikely able to get the equipment else where as the typical Medicare patient that needs a commode cannot travel to a store to purchase a 24 inch by 24 inch by 24 inch item on their own. It also typically does not fit in a standard compact or mid-size automobile. This patient will most likely not pay for the equipment to be delivered for an additional fee. The patient may likely not get the prescribed equipment at all. It is conceivable that this patient may have a home fall due to the lack of proper equipment, placing extra costs

and utilization in Medicare Part A programs such as Hospital, rehab and or future Home Health nursing.
- This also brings into question the ability to discharge the patient from the hospital in a timely manner. As liability issues often do not allow for the patient to be discharged without the proper home medical equipment in place. This will also create increased costs and utilization for Medicare Part A. The program may save money in Medicare Part B but again will substantially increase costs for Medicare Part A.

There are many specific issues related to the process of bidding and the expected results of once this process is in full effect. Therefore we again we request the opportunity to have a representative discuss these and other findings that AMEPA has discovered at the hearing.

Statement of Robert Brant

The issue at hand is the Competitive Bidding for Durable Medical Equipment, Orthotics, Prosthetics and Supplies. We have over 100 members that feel that they have been disqualified erroneously or have failed to win a bid due to the poor implementation of the program by the Competitive Bidding Implementation Contractor, Palmetto GBA, LLC.

There have been several problems with this new bidding process; from manipulation of application rules, the rejection of standard REGFLEX policies as required by law and the erroneous disqualification of 63% of the applicants with no ability to appeal. Senators, Congressmen and senior legislative staff have identified these problems as "gross negligence" by the Center for Medicare and Medicare Services (CMS). The results of which will be a limiting of access by patients to much needed care, unqualified companies will be providing incomplete services and major metropolitan areas will be grossly underserved during times of emergency. In addition 17,000 to 21,000 gainfully employed Americans will lose their jobs.

I have included the following attachments and would like to discuss the following developments:

A provider from Texas, which has won the Oxygen Category in 9 Metropolitan Statistical Areas, never provided the item before outside of their own area. According to Florida State records, the company is not licensed by Florida's Agency for Healthcare Administration as a Home Medical Equipment Provider. The Bid Winner does not have a License to deliver Oxygen from the State's Department of Health either. I am not sure that the company has an Occupational License in the State either.

The first line in the Rules For Bid (RFB) states that "All suppliers must—meet any local or state licensure requirements, if any for the item being bid" Clearly this bid winner did not meet the requirements for the bid he won in Miami and Orlando. I also believe that it was not the intent of Congress to allow something like this to happen.

According to the Rules For Bid (RFB) companies were required to prove that they could cover the complete geographical area of the MSA prior to bidding. The attachment proves this Bid Winner did not have any subcontract agreements in place before they bid, as they are currently fishing for providers to do their work.

This bid winner and other out of state bid winners should clearly not win the bid for oxygen and CPAP. Their bid should be disqualified for not meeting proper licensure requirements. When their bid is disqualified, their bid price should be removed form the Composite Bid and all of the pricing would be affected and other bid losers should take their place.

Another attachment is from a bid winner in Miami and Orlando. This winner has changed their policy and as of April 1, 2008 (not July 1, 2008) they are refusing to deliver a commode or other bath safety products unless the order accompanies Oxygen or another rented item. Providers currently compete in the market by providing equipment at a low margin in order to keep the referral source happy. Now the bid winner does not have to compete for business and is refusing to provide these Medicare covered items which are not subject to the bid as they are considered inexpensive. If the Bid winner will not provide these bath safety products then who will provide them?

This proves that the program will limit the patient's access to care. If the patient cannot get their prescribed medically necessary equipment from a bid winner they are unlikely able to get the equipment else where as the typical Medicare patient that needs a commode cannot travel to a store to purchase a 24 inch by 24 inch

by 24 inch item on their own. It also typically does not fit in a standard compact or mid-size automobile.

This patient will most likely not pay for the equipment to be delivered for an additional fee. The patient may likely not get the prescribed equipment at all. It is questionable that this patient may have a home fall due to the lack of proper equipment and that would put extra costs and utilization in Medicare part A programs such as Hospital, rehab and or future Home Health nursing.

This also brings into question the ability to discharge the patient from the hospital in a timely manner. As liability issues may not allow for the patient to be discharged without the proper home medical equipment in place. This will also create increased costs and utilization for Medicare Part A. The program may save money in Medicare Part B but again will increase costs for Medicare Part A.

Statement of Ryan Stevenson

According to the MLN Matters #SE0807 about competitive bidding, "Beneficiaries who are receiving oxygen, oxygen equipment or rented DME at the time the competitive bidding program becomes effective may elect to continue to receive these items from a non-contract supplier, if the supplier is willing to continue furnishing these items". It also states "if the beneficiary stays with a "grandfathered" supplier, he or she may elect to change to a contract supplier at any time, and the contract supplier would be required to accept the beneficiary as a customer".

According to current Medicare guidelines, oxygen rents for 36 months, and then is capped. What happens to the contract supplier that has a beneficiary come in to their store that has had oxygen for 35 months with a non-contract supplier and decides to switch to that supplier? They are force to provide oxygen to a beneficiary for one months rental, and then give the beneficiary that equipment because is has capped.

Who is to stop non-contract suppliers from recommending to there patients to do just that, so that after 35 months, they could get new equipment?

Statement of Tennessee Association for Home Care

Views regarding the credibility and viability of the recent low bid companies that saturated Round 1 are doubtful to dismal in the minds of most industry leaders across the nation. Nearly everyone was surprised by these prices. They were much lower than anyone expected and much lower than most existing companies with heavy patient demand feel can be safely managed. Even the national companies, some of which won no bids in some of the MSA sites bid out, were surprised at the final price of the bids. How did it happen that far too many of those who studied the program the most, who know their business the most, and who know better than anyone what it takes to provide the products and services to patients in an efficient, cost effective manner now are surprised and many cases eliminated by providers who say they can do it cheaper? Even CMS forecasted savings 10% less than these prices as recent as 2006 according to its final rule for Round 1.

Is this the great price savings that CMS has bragged about for weeks, or is this actually a red flag that may already be signaling some of the systemic deep problems with the competitive biding program? This question is critically important and must be answered, especially in light of the unexpected and radically wide range of prices received in these 10 MSA Round 1 zones. We have to find out the answer to this and several other questions before we go further into this uncharted water. Although HME providers currently do not have the authority to obtain this and other important information from CMS, Congress must make sure that they receive and review these answers and represent the effected Medicare population before this test program advances further. It is relevant to know how many of the bid winners have never provided services in the bid area before and how many intend to ship most of their products to patients via UPS. It is important to know who these companies were that sent in these low bids. What percentage of these companies did not follow through and actually sign their winning bid award that was used to calculate these low prices? For those that did sign the contract, what percentage of them are not currently prepared today to immediately take on significant amounts of business in the MSA market they won?

We also need to know more about who did not get offered bids. We need to know the number of small business bid losers as well as those who simply did not try to bid knowing they could not keep up with the added costs and reduced fees. If this program was intended to find the true market price, why did so many bidders have their bids kicked out and rejected entirely because their bids were higher than the predetermined limits manipulated and set by CMS? In essence, CMS imposed a superficial and unrealistic glass ceiling resulting in CMS arbitrarily kicking out all bids that did not meet its contrived preset charge limits, resulting in only an extremely small remnant of provider bids surviving this arbitrary award process. These results have now been disingenuously presented to Congress under the banner of true competitive bid market prices that saves 26%. How can such a decision of capriciously and recklessly eliminating large numbers of bidders that submitted charges over this erroneous glass ceiling, who in good faith submitted real market price bids, be allowed to be called a true market prices from an open bid process? Since the original intent of Congress with this competitive bid program was to find true market prices available in each MSA community, all bids should have been allowed in the setting of the price rather than only those bids that were arbitrarily filtered and hand picked by CMS. If Congress had wanted CMS to arbitrarily reset prices for these products this way without regard to the true market prices submitted by all providers, this could have been done much more simply without all the expensive and burdensome process of a competitive bidding process which will cost the government hundreds of millions of dollars a year to run. How many previous small business providers (as defined by the Small Business Association—not CMS) just got eliminated from the marketplace due to this careless process, and what will be the impact on the patients in those communities?

John Gallagher, Vice President of Government Affairs for VGM Buying Group, who represents over 3,500 independent Home Medical Equipment Providers, had some very interesting public comments about this at the recent Tennessee Association for Home Care Spring Conference held on April 1–3, 2008, in Nashville, Tennessee. He stated "VGM believes that although CMS has stated that small business providers won 64% of the bids, by VGM's calculations, 95% of the small businesses in the marketplace were actually eliminated." There are growing suspicions now that far too many of the bid winners do not have locations within the MSA market they have been awarded bids for. It is highly likely that groups of products were actually bid by out-of-state bidders who fully intend to ship the products into that marketplace rather than offer them via an existing brick and mortar storefront with accessible staff. This begs the obvious question. Just how many bid winners are not currently operating in each MSA they won—and never will?

Several weeks ago I received a phone call from a Tennessee provider who has inside information on a small local pharmacy in St. Petersburg, Florida, who won the CPAP bid in 8 of the 10 bid areas for Round 1. The pharmacy reportedly has no experience with this kind of volume of business. The pharmacy owner reports that he is not planning to open locations in each MSA but will drop ship all the products via UPS. In Tennessee, CPAP items are one of six respiratory items that by state law may only be fitted on a patient in the home by a licensed respiratory therapist. Most patients require extensive training; over a period of several months many need setting adjustments to their CPAP equipment and often require a change of mask to for a better fitting to obtain patient compliance with the therapy. Patients using this type of product need a local provider available to them. Unless the patient obtains a good fitting and works closely with their provider, the investment in their product by Medicare will be of no value. There is no savings on a product that has so poor a service component with it that patient ends up not using it. Although this particular provider in Florida can not be identified due to a confidentiality agreement between the pharmacy owner and the source for this information, it can certainly be used as a starting point for congressional investigation into the over all nature of this competitive bid model that would result in this type of bid award. It reveals just how these prices actually ended up lower than expected and lower than what most industry experts say is viably possible. I do not believe this type of scenario was how Congress expected competitive bidding to be carried out by CMS.

This model also could very likely be imbedded in all the bids throughout the country for several product categories. Whether these companies whose winning bids are structured with plans to simply ship the products in, later place a storefront there, or not even sign the contract once offered, it is all the same in one regard: an extremely large number of bid winners and price setters very likely are not tried and true tested businesses that are capable and willing to provide significant amounts of products and services into that local bid market. Many are nothing but speculative start-ups or companies with risky accelerated branch growth plans into these

markets. Medicare patients deserve better. For legitimate quality providers who want this privilege and want the option of growing their business into these new markets, the option may seem fair. However, a realistic view of the players who did this might soon wipe out all the fairness in this opportunity as it exists in this current competitive bid model. This option may very well have opened the door to careless opportunists, insincere players, and companies set on gaming the system causing damage to the price formula. Companies new to a MSA can claim the smallest of all capacities in order to qualify as a bid, yet their price weighs as much as the largest company in the MSA. As currently designed, the competitive bid program lacks the checks and balances needed to separate these types of bidders from more capable, serious providers. The bidding program must be delayed immediately to prevent this from harming patients. The system as designed does not prevent speculative type bidders from having as much weight and price effect as those heavily invested and currently accountable to large patent populations within the MSA. As result, bids from providers outside the MSA should not be factored in the pricing of the MSA. Providers currently with no operations inside the MSA should only be allowed to be factored as eligible bidders from a capacity perspective if their bid is low enough, but their bid offer should not be factored in the final MSA price. Outside bids are too arbitrary, meaningless, and unaccountable since they have no current or any guaranteed future obligation to service patients in that MSA. As such, there is absolutely no credibility in the 26% savings initially announced by CMS.

New problems associated with this new phenomenon are plentiful. Too many bidders were permitted to bid who have no significant current investment cost—or any risk for that matter—related to the submission of their speculative bid into these markets. Even if their lower bid causes them to be offered a contract, they can simply say no to the offer without losing any preexisting revenue or profit streams from that market. The bid, however, remains in the formula for that MSA affecting other providers as if it was valid. This careless unreasonable decision is another example of why CMS must have more accountability and Congress must permit judicial review for this program. Should the low bidder from outside the market choose to sign a contract, they would also be able to do so with unfair and unreasonable options not available to the other bidders located in the area with preexisting business revenue. In fact, under the current competitive bidding rules, the new company could operate in a way that they could choose to never take on any significant revenue by limiting their marketing for their services. In essence, they become a bid winner with nothing invested and nothing to lose, but they have equal power to change the "reasonable price" of that market even though they have no real accountability or risk to prove the price is in fact reasonable (more reason to not factor their bid in the final price). If and when they begin operations, if things do not work out, they can simply close operations and leave before they make too sizeable investment into the marketplace. The failure of this system is that the weight of their bid is equally as heavy as the bid of an existing company who is fully invested with the necessary overhead required to legitimately run a HME program and already burdened with the heavy demand of existing patients.

The real world cost of doing business is naturally and rightfully factored into the bids of pre-existing providers in a MSA. In general, their bids should in most cases be higher. Speculative bidders and bidders who would have the right to enter the marketplace in a timid and cautious manner do not have the same risk factors as existing providers. This is unfair and unreasonable gaming of the system at its worst. More importantly, they do not have the same responsibility or accountability to immediately provide for the needs of the Medicare patient community in ways that can predictably be assured or in ways that preexisting companies must factor into their bids. Bid winners new to a MSA with no current operation there should suffer significant penalties if they fail to fulfill their bid capacity obligation assigned to them at the expense of an existing provider who is currently providing services to beneficiaries. No such penalties exist under this competitive bid model. Their current lack of accountability to the program and the patient community disrupts and discredits the entire competitive bid system and puts patients at risk. This problem and the fact that their low bids weigh the same as a high volume bidder are two critical key issues that must be cured before the competitive bidding program is allowed to continue. As the model is currently designed, companies bidding in a new MSA are free and able to be bid spoilers with no risk, no loss, and no consequences for placing a bid that is below their actual ability and in many cases their will to perform. This is simply wrong.

These speculative bidders who have nothing to lose may well have damaged the integrity of the entire bidding process in Round 1 with their low speculative bids, and they could lead to destroying the entire viability of the competitive bidding program in the future rounds if the model is unchanged. This should never have been

permitted. The model is flawed. Two separate competitive bidding financial studies predicted such gaming of this system, and one notified CMS as early as 4 years ago that this would occur. More detailed information about both of these studies will be presented as part of the comments to the House Ways and Means Committee today by the American Association for Homecare. CMS has paid no regard to such warnings and therefore has now permitted the systemic problems related to the poor design of this competitive bidding model to begin to recklessly and dangerously eliminate a large number of legitimate cost effective providers in these Round 1 MSA communities. This is poor public health management and irresponsible government at its worst, yet there is no judicial review, no due process, and no regulatory oversight in place to investigate, mitigate, or cure any of these problems. Our legislators deliberately granted CMS the ability to run this program unchecked as they saw fit regardless of its potential harm to Medicare patients, their families, and the HME provider network. This must be reversed. It is simply un-American.

I suspect if we could go further into the peeling off the onion, we would find more and more areas that prove this program, in its current format, stinks from one end to the other. Therefore, it is critically important that Congress quickly recover from the initial intoxication of the announced 26% savings and look at the real picture. Congress must intervene immediately before it is too late, requesting a delay in Round I and Round II and demanding needed transparency of these issues so that these pitfalls can be identified and altered before they are allowed to harm patients and destroy a large portion of the quality providers throughout these MSA communities all over the country.

Statement of Wayne E. Stanfield

There is a crisis facing over 40 million Medicare beneficiaries called Competitive bidding for durable medical equipment (DME). On behalf of those patients served by over 113,000 DME suppliers, I am writing to ask for your help.

The Medicare Modernization Act of 2003 (MMA03) included, in 10 of its 415 pages, a sweeping change that is now being implemented. This portion of the law, giving broad power to the Center for Medicare and Medicaid Services (CMS) and removing all due process from suppliers, will have a devastating impact on Medicare beneficiaries who need care in their homes. This program puts the most needed categories of medical equipment out to the lowest bidders. It will begin July 1, 2008 in 10 cities and will expand to 70 additional cities next July.

The outcry from this small but vital component of patient care has not been heard and we ask for your support to end this pending disaster about to affect millions of lives. CMS has turned a blind eye to the true impact this ill-conceived program will have on the lives of our seniors.

This is bad public policy and in reality there is nothing competitive about a process that will reduce access to physician ordered medical equipment for Medicare patients at a time when that population is growing everyday by 7918 seniors who turn 65 year old.

For more than four years patient advocates, political leaders, DME industry leaders, and economists have advised members of both the House and Senate of this impending train wreck. Now is the time to act on this matter and we ask you to intervene. Economic studies clearly indicate that this program will harm patients and will decimate tens of thousands of small businesses in every state.

Congress must stop the implementation of this program before it is too late. I implore you to stand and be counted on this issue. The enclosed disk has a petition with signatures and comments of over 5000 Americans who clearly see the human disaster this program will cause. Included also are facts that have already come to light about the problems with the program as well as the studies produced by two leading universities.

We believe in our democratic process and know that Congress can act to stop this travesty from happening. As a spokesman for the patients and suppliers that will be so harshly affected by competitive bidding, I ask you to join other members of Congress in telling CMS to STOP implementing this program and I urge you to support legislation to repeal this portion of the MMA03.

Thank you for your support for this time sensitive, critical issue and look forward to hearing from you on this matter. Please contact my office if I can provide any additional information.

Statement of Zachary A. Schiffman

My name is Zachary Schiffman. I am the owner of United States Medical Supply, Inc., a licensed and accredited national durable medical equipment (DME) provider of primarily mail-order diabetic supplies employing over 170 people in Miami, FL. As an accredited DME provider for over 10 years, we support Medicare's efforts to save money and reduce fraud; however, CMS's (Center for Medicare & Medicaid Services) Competitive Bidding Implementation Contractor (CBIC) has not performed its fiduciary responsibility to run a fair process in the DMEPOS Competitive Bidding Program mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. I am requesting the committee petition to CMS to stop and reevaluate the competitive bidding program due to the implementation contractor's complete bungling of the bidding process. I urge this on behalf of myself, my company, the Medicare program's integrity, the DME industry, and all Medicare beneficiaries.

History of events

Medicare was charged by the MMA Act of 2003 to institute competitive bidding program for DME items initially in 10 cities and then to roll it out in phases nationally. To institute the program, CMS hired a Competitive Bidding Implementation Contractor (CBIC). The CBIC failed in its job to properly administer the program in many ways most notable being 1) the bid price; and 2) the bid capacity; and therefore this first round of bidding must be halted and reassessed immediately.

Bid Price

The CBIC was supposed to ensure the integrity of bids by ensuring that low ball bidders did not corrupt the system. The CBIC failed to perform this fiduciary duty. Case in point, mail order diabetic supplies were dealt a 43% drop in reimbursement as proposed by the CBIC. At first glance, this would appear to be a windfall savings for the Medicare program. It is not. This low price is the result of low ball bidding by unsophisticated mom and pop operations and a few unscrupulous larger low ball bidders. We have personally conducted interviews with some of the winning bidders and can attest that they consciously bid below what they could realistically provide in order to just "win the bid."

The CBIC requested financial statements from all bidders. A simple analysis by the CBIC of these financial statements would have shown that a 43% reduction in reimbursement was unsustainable and unprofitable for even the lowest operating cost companies. This analysis could have been easily been performed by the CBIC simply by reducing a company's revenue line by said company's proposed percentage discount of the company's bid versus the current allowable price paid by Medicare. With keeping all expenses the same, a new "post bid" net income could be attained. I can assure you that no legitimate company in this industry would be in any way even close to profitable with a 43% revenue reduction. It could be said that perhaps some expenses could be reduced such as marketing and some trimming of the fat, but such cost savings would not nearly bring any company close to profitable at a 43% revenue reduction. In fact, with the small number of winning bidders, the winning bidders will have to make substantial capital investment to handle such capacity increases (see capacity section) and with such a cut in reimbursement, there would be no money to pay for said expansion.

In example of the lack of proper vetting of low ball bidders, Liberty Medical (owned by Polymedica and since purchased by Medco) provides about 50% of the mail-order diabetic supplies to Medicare beneficiaries. Due to their sheer size and market dominance, they arguably have the lowest costs for product available. Their EBITDA (earnings before interest, taxes, depreciation, and amortization; and a close barometer of cash flow) margin is about 13% per SEC filings. Therefore, Liberty, the lowest cost provider, could not bid more than a 13% reduction in reimbursement and be able to sustain its business. Now, perhaps say they could trim some expenses and advertising. This could not account for increasing the maximum discount they could bid to more than about 20%. This is a far cry from the 43% reduction to be implemented by CMS as per the CBIC's negligent handling of this process.

Suffice it to say, Liberty (the 50% market share holder) did not win a bid. Neither did any of the other public companies that had a fiduciary responsibility to bid in such a way to run a sustainable business. Proof positive that the CBIC failed in its job to not allow low ball bidders.

The CBIC should have disqualified any bid that would have bankrupted a company by negating its profit margin or at the very least they should have changed said implied discount on low ball bidders bids to be equal to their EBITDA margin thus to not allow them to submit a price that they could not sustain.

The CBIC performed no such analysis. As per interviews we have performed with said low ball bidders, the CBIC simply asked to see invoices for products from extremely low bidders to determine if their bids were too low. Said bidders simply submitted invoices for their lowest cost, lowest quality off brands and the CBIC took the bids as the gospel with no analysis of other basic operating costs such as payroll, rent, etc., etc. In fact, the proposed bid price by the CBIC is below the actual contract prices of 90% of the manufactured products by market share such as those of Lifescan, Roche, and Bayer.

This in and of itself would be a travesty to let go further and Medicare beneficiaries will suffer with low cost, low quality products much less if these low ball bidders even remain in business.

Bid Capacity

The CBIC was supposed to ensure the integrity of bids by ensuring that the selected providers would be able in total to service the capacity demand of the markets they service. The CBIC failed to perform this fiduciary duty. The CBIC requested all bidders estimate the capacity increase that they could absorb if they won a bid. The CBIC was supposed to assess whether this proposed capacity increase was indeed accurate and throw out the bids of providers who overstated their potential capacity to block out other providers. The CBIC appears to have done no such analysis.

In mail-order diabetic supplies, there are over 500 providers. Only about 20 companies won bids. What are the other companies to do? In fact, the top 3 companies, Liberty, CCS Medical, and Access Medical, totaling a market share over 75% did not win bids. In order to meet the same capacity of these top 3 providers, the CBIC would have had to select more than the next 50 providers. They obviously did not. The drop off in volume of the providers past the top 10 drops off so substantially that providers 11 to more than 200 would have to be selected to reach the same capacity as the top 3 providers. Since less than 20 providers won and none of the top 3 won AND at least 25% were mandated to be small providers, it is obvious that the CBIC made no efforts to ensure that unscrupulous bidders didn't bid low and grossly over estimate capacity to knock legitimate companies out of the process.

At the very least, the CBIC should have capped any provider's given capacity increase to an arguably aggressive 20–50% over the capacity for the previous year. They did no such thing. In fact, given that it is obvious that the CBIC accepted tremendous capacity increase estimates from its bidders, substantial capital investment will be required by these providers. As per the extremely low bid prices (see previous section) these winning bidders will have no resources to even attempt to achieve these capacity increases let alone the fact that the creation of a growth platform takes not only money, but time in numerous regards such as acquiring space, training people, implementing infrastructure, etc. In fact, The CBIC proposes that these winning bidders (who will obviously have to substantially increase their capacity beyond reason) begin to be the sole providers to Medicare beneficiaries for the product categories they won in 3 months! Another example of the bungling of this process by the CBIC.

In light of the above, I implore you to make all due haste in stopping the DME Competitive Program until the CBIC can justify its methods in light of the above obvious errors.

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