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SUBCOMMITTEE HEARING ON COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT

SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP
COMMITTEE ON SMALL BUSINESS
UNITED STATES HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MAY 21, 2008

Serial Number 110-95

Printed for the use of the Committee on Small Business

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

40–860 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
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SUBCOMMITTEE HEARING ON COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT

Wednesday, May 21, 2008

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:12 a.m., in Room 1539, Longworth House Office Building, Hon. Heath Shuler [chairman of the Subcommittee] Presiding.

Present: Representatives Shuler, Clarke, Fortenberry, and Davis.

Also Present: Representatives Velázquez, Braley, and Gonzalez.

OPENING STATEMENT OF CHAIRMAN SHULER

Chairman SHULER. This hearing for ″Competitive Bidding For Durable Medical Equipment″ will now come to order.

First of all, I want to thank everyone for being here. For a Subcommittee hearing, we have standing room only, which is quite remarkable. I think that I told the ranking member here, Mr. Fortenberry, I said, wow, this is great. He said, well, they are not here for us. But thank you for being here and being actively involved in this due process. I think that is what makes our country so strong.

Access to health care is becoming increasingly critical for our Nation's seniors. By 2015, the baby-boom population in this country will reach 77 million. So it is critical to consider how we will care for these older adults and how we pay for that care.

In 2007, health-care costs in the United States reached $2.3 trillion. Without a doubt, this is one of the greatest challenges of America, and if we are not careful, it will bankrupt our Nation.

The question before us today is whether addressing America's Medicare challenges requires hurting small health-care providers who have committed themselves to serving our seniors. This hearing will examine the implications of the competitive bidding process for durable medical equipment. While this program was created as a way to curb Medicare spending, this Subcommittee will review if CMS is properly considering the impacts on small health-care providers.

CMS maintains that competitive bidding will not only ensure access to care but reduce out-of-pocket expenses for seniors and improve the effectiveness of payment. However, it is not clear that the program will meet the goals without driving health-care providers out of business and eliminating access to care.

The results for the first bidding program were mixed at best. CMS's competitive bidding program for durable medical equipment was implemented in 10 cities last year. The bidding process created a number of problems for durable medical equipment small-business providers. CMS incorrectly disqualified some companies from participating due to clerical problems. In a number of situations, contracts were awarded when the bidder had no local presence, no history of providing a given product or service. This clearly does not meet the goal of ensuring access to care for the beneficiaries.

Since Asheville, North Carolina, is in the second round of competitive bidding, I have been hearing about this problem on a first-hand basis. Small firms are an essential part of the health-care market, as they will fill many of the gaps larger businesses either cannot or will not fill. Like a number of my colleagues, I am worried that CMS has not considered the unintended consequences that may result from this program.

This includes the possibility that Medicare beneficiaries may lose the right to choose the trusted care and the services of their local provider. Eliminating suppliers could have a devastating impact on rural communities. Suppliers could have to limit the outreach to rural areas. At the time when these communities are already facing health-care shortages, CMS should not be making this problem worse. Also, I believe that rural communities would be unfairly impacted by competitive bidding because of the nature of this program. Health-care practices could be forced to close their doors and working families would lose their jobs.

Unfortunately, CMS has not taken any corrective action to fix the competitive bidding process and the impact it will have on small suppliers. I think everyone in this room agrees that the Federal budget simply cannot sustain the current growth rate in Medicare spending. However, we must also ask, is there a better means to achieve this program?

I look forward today to hearing the testimony. I thank the witnesses for their participation.

At this time, I will yield to the ranking member, Mr. Fortenberry, for his opening statement.

OPENING STATEMENT OF MR. FORTENBERRY

Mr. FORTENBERRY. Well, thank you, Mr. Chairman, for holding this important hearing.

And we thank you, as well, for attending today.

The House Small Business Committee, this Subcommittee and our Nation recognize that small business is critical to the country's overall economic well-being. The competitive pressures, creativity and innovation that small businesses bring to the marketplace are the hallmarks of entrepreneurship and the keys to job creation and economic growth.

In many areas of our economy, the needs of rural America are uniquely different than those of urban areas. Few issues are more important to rural Nebraskans, for instance, than access to quality health care and services and providers. Small businesses particularly depend on access to quality health care as a key component of efforts to attract and retain a vibrant workforce. Small employers also play an important role in the delivery of health-care serv-

ices and products in many rural markets. For example, 103 of the 142 pharmacies in my district are small, independently run employers.

As we all know, Congress, in 2003, mandated that the Centers for Medicare and Medicaid Services implement the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program. It is, therefore, appropriate that Congress and we provide oversight as this program moves forward.

The competitive bidding program was established to reduce beneficiary out-of-pocket expenses and save taxpayer dollars, while ensuring beneficiary access to quality items and service.

The Centers for Medicare and Medicaid Services is scheduled to implement the competitive bidding process in phases, as our chairman reviewed. Round one encompasses 10 competitive areas and is ongoing. Round two encompasses 70 competitive areas to be implemented in 2009. And additional areas are to follow after 2009.

As a part of the bidding program, CMS is required to take appropriate steps to ensure that small suppliers have an opportunity to be considered for participation. Congress, through its oversight role, must ensure that this process is implemented in a way that does not impede the competitiveness of our small pharmacies and suppliers, particularly in rural areas. Many small firms remain competitive by delivering high-quality services and care to their patients. As CMS goes forward with this program, it is important to ensure that smaller suppliers, who particularly emphasize quality services, are left in a competitive position.

Mr. Chairman, I believe we have excellent witnesses here today to provide insight into what issues need to be addressed to improve this program.

Thank you again, Mr. Chairman, and I yield back the balance of my time.

Chairman SHULER. Thank you.

At this time, I would like to introduce the chairwoman to the Small Business Committee. I think it is a perfect example of her continued commitment and exemplifies her commitment to small business.

At this time, Chairwoman Velázquez.

OPENING STATEMENT OF CHAIRWOMAN VELÁZQUEZ

Ms. VELÁZQUEZ. Thank you, Mr. Chairman, Chairman Shuler, and Ranking Member Fortenberry. Thank you so very much for holding this hearing.

Mr. Wilson, if you look around this room, we hold hearings almost every week, it has never been this packed. I don't think that it is because of Mr. Shuler. It is because of the issue.

So I want to thank Mr. Shuler for this important hearing. He has been an advocate for small business on a number of fronts. Whether it is addressing energy costs, health costs or any other small-business concern, he has made small business his priority.

Congress must not forget that most durable medical equipment suppliers are not only important small businesses, they are a vital part of this Nation's health-care safety net. Every day the elderly depend on DME suppliers for medical guidance and support, and

they are often the only—the only—medical assistance some patients see in their community.

Once again, I find myself before CMS and the health-care community asking the question, why has the agency ignored the impact on small health-care providers? Over the past month alone, the Small Business Committee has held three hearings involving the Centers for Medicare and Medicaid Services. I don't think I would be alone in saying there is a problem. My concern is that CMS has little regard for how its decisions are impacting small businesses providing care for America's elderly.

I have heard from numerous health-care organizations and providers asking this committee to conduct oversight. CMS, like any agency, must be accountable. And today's hearing is as much about accountability as it is about the challenges of the DME program.

Again, thank you, Congressman Shuler and Ranking Member, for holding this hearing. And I yield back the balance of my time.

Chairman SHULER. Thank you, Madam Chair.

At this time, I would like to introduce Mr. Braley, our colleague and my classmate.

Welcome to our committee.

OPENING STATEMENT OF MR. BRALEY

Mr. BRALEY. Thank you, Chairman Shuler. And I would like to thank you and Ranking Member Fortenberry by not using the usual recording of ″Rocky Top″ and the Nebraska fight song to begin the hearing. We all appreciate that.

I would also like to thank Julie Weidemann, a constituent from my district and director of Palmer Home Medical Supply, for taking the time from her busy life to coming come to Washington, D.C., to testify before the Small Business Subcommittee on Rural and Urban Entrepreneurship on this important issue.

I grew up in rural America, and I represent a large district that has many, many rural communities in it. And that is why this issue is so important to my constituents back in the 1st District of Iowa.

In 2003, Congress passed the Medicare Modernization Act, which required the Centers for Medicare and Medicaid Services to launch the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program. While on the surface this may seem like a good idea, there is evidence that it could have devastating impact on DMEPOS industries.

Companies currently receive a Government-set fee to distribute durable medical equipment for patient home use. Under the competitive bidding system, however, companies would have to submit a bid indicating how low of a price they would be willing to accept. Medicare would then limit distribution rights in a particular geographic area to the lowest bidders.

In 2007, the DMEPOS Competitive Bidding Program started in the 10 largest metropolitan statistical areas, and in 2009 it is scheduled to be expanded to the largest 80 MSAs.

I have many concerns about this competitive bidding process. This year I joined many of my colleagues in sending a letter to CMS. In this letter, we expressed concerns with the level of small-

business participation in the competitive bidding program. Even the small businesses who are awarded contracts will be challenged to conduct business at reduced reimbursement rates because they cannot compete with large companies that have economies of scale.

Also, there are many bidders that have been rejected by CMS on claims they had not submitted sufficient financial information or they had made other minor errors on their applications. Although these rejected bidders have made claims that have evidence to the contrary, they have no appeal rights, which seems contrary to our Nation's fundamental premise of due process.

Furthermore, the program requires supplier accreditation for those participating in this program. This can create significant administrative and financial burdens on small suppliers and pharmacies. Many of these suppliers and pharmacies are already required to have a number of accreditations for providing care.

The biggest concern I have, however, regarding CMS's proposal is that it could put small providers like Palmer Medical Supply out of business. Palmer Home Medical Supply currently serves 10 counties in rural northeast Iowa, and almost half of their business involves Medicare beneficiaries. The potential loss of suppliers could threaten these rural areas, which are more likely to have elderly populations, including the fact that Iowa has one of the highest levels of elderly populations per capita of any State in the country. It is essential that our communities continue to have access to high quality and great service from these small-business providers.

I understand that the intent of the DME competitive bidding program is to provide cost savings for the Medicare program and its beneficiaries, and we all appreciate those efforts. But we need to ensure that beneficiary access, quality of care, and small businesses are not harmed by this program.

The CMS competitive bidding for durable medical equipment project leaves too many questions unanswered. We need to take a step back to think about the true impact this project would have on the small providers and, ultimately, on the communities where they reside. It is important to explore whether there are rational alternatives to determining Medicare pricing for DME items and service. There are too many indications that the current bidding system is flawed.

I look forward to hearing from our witnesses today, and I am hopeful that we can come up with a solution for Medicare reimbursement that does not pose so many potential risks for the providers and the patients they serve.

So thank you, Mr. Chairman.

And thank you to all the witnesses who have come so far to be with us today.

And I yield back.

Chairman SHULER. Thank you, Mr. Braley.

Our first witness is Mr. Laurence Wilson from the Centers for Medicare and Medicaid Services. Mr. Wilson is the director of the Chronic Care Policy Group in the CMS's Center for Medicare Management.

Mr. Wilson, thank you and welcome. You have 5 minutes for your testimony.

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

Mr. WILSON. Thank you, sir.

Good afternoon, Chairman Shuler, Representative Fortenberry, and distinguished members of the Subcommittee. I am pleased to be here today on behalf of CMS to discuss the Durable Medical Equipment Prosthetics, Orthotics and Supplies Competitive Bidding Program.

This important initiative, required under the Medicare Modernization Act, has three key parts: quality standards and accreditation, financial standards, and competitive bidding. Together, these will help reduce beneficiary out-of-pocket costs, improve the accuracy of our payments, help combat fraud, and ensure beneficiary access to high-quality items and services.

First, the quality standards and accreditation program and use of financial standards provide important safeguards for beneficiaries in the Medicare program. These safeguards also ensure a level playing field for suppliers competing under the competitive bidding program. Any bidder that failed to meet quality and financial standards was not qualified to participate in the program. The quality standards and accreditation program ensure that beneficiaries receive good customer service and have access to quality products from quality suppliers.

CMS conducted a wide variety of activities to involve stakeholders in the development of these standards. Many, such as focus groups for small suppliers, were important parts of the development.

The financial standards ensure that contracts only go to sound businesses that are capable of meeting beneficiaries' needs for the long-term. Financial standards also help weed out fly-by-night operators that prey on Medicare and beneficiaries, in contrast to legitimate suppliers acting in the best interests of their patients.

Under the competitive bidding program, qualified suppliers compete on price to be contract suppliers with Medicare. Contract suppliers then compete with each other based on quality and customer service to serve the beneficiaries in an area.

CMS adopted numerous approaches to ensure small suppliers have the opportunity to participate. First, CMS worked closely with the Small Business Administration to develop a more targeted and new definition of a small supplier. CMS then designed policies linked to this definition to help small suppliers in the program. For example, suppliers are able to band together in networks in order to meet certain program requirements.

The program also ensures a formula to provide that multiple contract suppliers are selected for each of the 10 product categories. Most importantly, there is a 30 percent target for small-supplier participation in the program. If the winning group of suppliers is not composed of 30 percent small suppliers, CMS added small suppliers to the list of winners to reach this target.

The initial round of competitive bidding is now complete, with the announcement of 325 contract suppliers this past Monday. We are pleased with the results. Twenty-three percent of the bids submitted were in the winning range. Sixty-one percent of the bids

were priced higher than the winning range, though some of those were also disqualified. The remaining 16 percent would have been in the winning range; they were also disqualified.

In the initial round of contract offers, 64 percent of the contracts were offered, again, to small suppliers. Ultimately, about half the contracts signed were those associated with small suppliers, clearly exceeding our target.

When the new payment rates take effect on July 1 for the first 10 bidding areas, beneficiaries will begin saving money on 10 of the most commonly used durable medical equipment products, such as power wheelchairs and oxygen equipment. The average savings in their co-insurance and Medicare payments will be 26 percent.

We understand that the implementation of this program may be difficult for some suppliers because the law anticipates that there must be both winning and losing bidders. Nonwinning bidders may still have opportunities to serve Medicare beneficiaries through providing nonbid products, subcontracting arrangements with winners, or as grandfathered suppliers for certain items, or by providing repairs and maintenance.

We also understand that the new system represents a significant change in how suppliers operate under Medicare compared with the past. And we will continue to work closely with suppliers and make improvements in the program as we move forward.

CMS is also conducting aggressive education and outreach to be sure that every beneficiary partner and supplier knows how to use the program well and ensure a smooth transition on July 1. CMS will also monitor the performance of contract suppliers through beneficiary satisfaction surveys, tracking the volume of questions and complaints that CHIPs and 1-800-MEDICARE receive. These and other activities will help us keep current on what is taking place on the front lines.

In conclusion, CMS is committed to the success of this program. We have designed a program to provide beneficiaries with quality items and good customer service at a lower price from reliable suppliers.

I very much appreciate your time today and the invitation to testify. I would be happy to take any questions. Thank you.

[The prepared statement of Mr. Wilson may be found in the Appendix on page 63.]

Chairman SHULER. Thank you, Mr. Wilson, for your testimony.

The first question I have, in the first round of the bidding process, a Texas-based supplier won a bid that serviced Charlotte, North Carolina, a Texas-based company.

How does CMS evaluate the bidder's statement of capacity when the provider has no offices, no employees in Charlotte?

Mr. WILSON. A very good question.

Consistent with how the Medicare program currently works, there are providers that operate out of State and move into new areas. Some suppliers are setting up subcontracting arrangements. Some may have distribution centers on the ground.

Just yesterday, we talked to two suppliers that were moving into Pittsburgh. They already had, while they are listed in another State, they already had a distribution center on the ground. One

of them already had existing contracts with University of Pittsburgh Medical Center and had been supplying services through W-2 employees in Pittsburgh for years.

So we think there are a lot of those type of arrangements being made. We are checking on these ones that are listed as out-of-State suppliers, because we think the issue you raised is an important issue. We want to make sure that the suppliers have a plan in place to provide services, provide access to our beneficiaries.

And, in fact, through the bid process, we did ask for subcontracting information from suppliers, because we wanted to understand their expansion plans and know how they were going to provide services. And we are following through to check on it now.

Chairman SHULER. During the process, one of the qualifications was their quality. Specifically tell me how the quality is measured from a particular company.

Mr. WILSON. What the law requires—the Medicare Modernization Act provided this authority that CMS would establish a set of quality standards that independent accreditation organizations, selected by the Secretary, would use to go out, do on-site reviews, and accredit suppliers.

So suppliers need to have a plan for things like business standards, personnel, but also how to provide care. That is, working with physicians, how they are going to do delivery, set up of equipment, how they are going to monitor complaints, collect performance information, and keep that information for the accreditation organizations.

So we expect and require for this program, and will require nationally by September 30th for all suppliers, September 30th, 2009, that they be accredited in this manner. There are 10 private accreditation organizations currently accrediting suppliers.

Chairman SHULER. So you look at the quality based upon the business. You know, I have been in business for many years, and occasionally we have subcontracted. How is a business able to regulate, or how does CMS, how are they qualifying a subcontractor of a company?

I mean, if they are looking at quality based on that company, when in fact the supplier themselves is actually another company? If they are subcontracting it, what qualifications from the subcontractor has CMS taken in consideration?

Mr. WILSON. Right now we hold the supplier that we have a contract with responsible for meeting the requirements and ensuring that the beneficiaries are provided the appropriate services.

Do we have an accreditation requirement on the subcontracting suppliers? I don't think we have that requirement in place right now. I think that is something that we need to look at as we roll out accreditation nationally for September of 2009.

I think that is an important issue, because to the extent that suppliers have been subcontracting—and they have been for years—and we are moving into this world of accreditation, we need to consider what that relationship looks like. So I think it is an issue and one that we are looking at in the context of our progress on accreditation.

Chairman SHULER. So, in fact, a company could be awarded a bid through the process, it could be rewarded that contract, and they

could subcontract out to someone who was of substandard quality that you had actually already failed or denied?

Mr. WILSON. If they had failed accreditation, I think that would be a concern for us.

Chairman SHULER. So maybe that is something CMS should take into consideration?

Mr. WILSON. I think that is something we ought to look at. And to the extent that we are interested in looking at subcontractor relationships and accreditation for all suppliers—

Ms. VELÁZQUEZ. Would the gentleman yield?

Chairman SHULER. I yield to the chairwoman.

Ms. VELÁZQUEZ. Mr. Wilson, the subcontractors, would they be licensed by the State? Will that be required, to be licensed by the State in which they are going to be providing the services?

Mr. WILSON. I am not sure of the answer to that question.

Ms. VELÁZQUEZ. Don't you think that is an important answer?

Mr. WILSON. I think it is an important answer. I—

Ms. VELÁZQUEZ. Because it will determine whether or not they have the ability to provide quality care and services.

Mr. WILSON. I think we should do everything that we can to ensure that the beneficiaries get the services they deserve and that they are quality services.

Ms. VELÁZQUEZ. So what process are you going to have in place in order to make sure that appropriate oversight will be there to prevent those subcontractors that do not have the ability in the first place, because probably they submitted a bid and they failed? So if they fail, what do you think are the reasons for someone who submitted a bid and failing and not getting the award?

Mr. WILSON. I think, to the first part of that question, what we need to do is rely very heavily on monitoring, especially as we roll out the program on July 1. I think we need to do things like collect data from 1-800-MEDICARE. We are doing that. We need to do beneficiary satisfaction surveys to ensure that people are happy with the services they are getting. I think you raise an issue that we may want to focus on in doing that type of review.

We are also operating a program where, if there are concerns, they do arise, we will have ombudsmen, we have eight ombudsmen ready to work with beneficiaries and suppliers in each of the areas, or eight ombudsmen total that will be out there.

And so I think we need to be able to address those types of concerns.

Ms. VELÁZQUEZ. Okay, Mr. Wilson, when I asked you the question whether or not licensing is an important requirement and you said that you don't know the answer to that question, isn't that part of the Medicare rule, that licensing?

Mr. WILSON. I believe it is. They need to have a National Supplier Clearinghouse number, so they need to be enrolled with us.

And to the extent the State requires licensure, which I believe it does, then whatever the requirements are for Medicare enrollment, they must be met by the supplier.

Ms. VELÁZQUEZ. I yield back. Thank you.

Chairman SHULER. Obviously, we have indicated already a few of the many concerns and questions that the Committee has.

Name the biggest problem that you have run into in the first bidding process. And the second thing to do is tell me some of the things that you are able to correct of the major problems. And in order, what is the biggest difference between the first bidding process and the second bid process?

So, first of all, tell me the biggest problem that you have had in the first bidding process.

Mr. WILSON. The biggest problem that I think we had was with the tool that we used to interface with suppliers in the process, and that was the online bidding system.

There were problems with the online bidding system that caused a lot of frustration for suppliers. Again, bids were submitted electronically; hard copy documentation followed later. But bids were submitted electronically. The system would time-out. The system would lose information. That was a problem that we had to deal with.

We have taken that issue and, for round two, developed an entirely new system that we expect will not have those types of problems. That was a concern, caused us to have to extend the bid window and, again, caused suppliers a lot of frustration. So I think that is, sort of, to the point that we are now, the biggest thing that we want to do for the next round of competitive bidding.

The other thing I would add is that supplier education is always a key issue. To the extent that you have a new program, you have lots of suppliers across the country, you want to be transparent on the rules. We want to work on education. Learn from round one, where did people have concerns? Where were there problems in the bid? And focus our education on those issues.

And then, finally, the last thing I would mention is we are just now moving forward with a big national beneficiary education program in the 10 areas. And I think we are looking at that to see how that works, where we might need to make changes for next time. That is one of the key parts of this endeavor, educating the beneficiaries and those that refer beneficiaries for services.

Chairman SHULER. Is CMS completely prepared for the July 2nd bidding process?

Mr. WILSON. Well, we have not announced a timeline for the second bidding process. We have not said that we are going to open the bid window in July.

I think what we are doing right now is concentrating on round one in the 10 areas and ensuring that we are prepared to implement the system, meet beneficiary needs, and monitor to ensure beneficiaries get what they need. That is what we are focused on now.

I think in the coming weeks or months we will publish a timeline, specific timeline, for round two so that suppliers will know what they need to do to get ready for round two.

Chairman SHULER. Obviously, being a part of the Blue Dog caucus, we are very concerned about wasteful spending and being able to cut areas of wasteful spending in our budget when we are at a time of tremendous debt in our Nation's history and we are passing it along to our children and grandchildren. So, you know, I commend CMS from the standpoint of being able to save money.

What has been the overall value of savings? And the reason—and I caution when I ask this question, just the initial savings from the standpoint of from the suppliers' standpoint. But let's say, for instance, they are dropping off the equipment—basically a drop-off at a location, say, it's home oxygen care, they drop it off. Well, if they are not able to regulate it and able to manage it, and have basically the case management with that particular patient, how many of those patients ultimately end up in the emergency room or an ambulance ride, a $600 ambulance ride? How many of those?

So, in evaluating the equation of the overall cost, was that taken in consideration? How much savings were there in round one?

Mr. WILSON. I don't know if that type of a factor was—that type of qualitative factor was evaluated in round one. I am not sure how it would be.

I think the thing that we have tried to do to address the issue overall, which would seem to me to mitigate the financial impact or the economic impact of that type of, you know—

Chairman SHULER. Loss of jobs, unemployment, layoffs—I mean, all those have to be taken into consideration. You just can't look at the complete one implication when you say, ″We have a bidding process and we are going to be able to save money in the initial cost,″ when in fact more people are going to the emergency room, more people are getting an ambulance ride, more people are staying in the hospital, and ultimately more causes of health-care costs to rise. I mean, those have to be taken into consideration.

The loss of jobs from our small businesses have to be taken into consideration. How many people went from a company of 10 to a company of two because they are subcontractors now, not the initial providers?

I mean, all of those have to be taken into consideration for us, as Members of Congress, to help CMS to be able to help regulate. I am all for doing everything that we can to make sure that we provide—the quality of service has to be number one for the patient. But we also have to make sure that we manage it in the fact that we have the quality but we cut spending as best we possibly can.

And I think that all of us on the Committee would agree we have to do something with our health-care problem, but we can't provide more at cost and just as a pass-along to other industries. Because it ultimately is going to come down to the costs. And if we are not careful, then we are going to bankrupt our country on this health-care problem.

And, at this time, I will yield to the ranking member, Mr. Fortenberry, for his questions.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Thank you, Mr. Wilson, for coming today.

Clearly, reducing cost and at the same time improving quality of service is a goal we all share and, I don't believe, are incompatible.

You had mentioned that there is a 26 percent average savings. Did you mean that for the beneficiary or for the Government or in totality?

Mr. WILSON. I meant for both. So, compared to what Medicare currently pays under the fee schedule, which has been in place for about 23 years or so, prices under competitive bidding are, on average, 26 percent less.

So Medicare will be paying less, and beneficiaries, our most vulnerable population of elders, seniors, that pay a 20 percent co-insurance on that price, will also be paying less.

Mr. FORTENBERRY. I think it would be helpful to return to one of the questions that my colleague, Chairman Shuler, had raised regarding quality of service and unpack that a little bit further.

Is distance for a beneficiary to travel to a provider a part of the quality-of-service measure?

Mr. WILSON. Well, it is not part of the quality-of-service measure. It is an interesting question, because I think, in this industry, and if you look at the items that we bid, most of these items are delivered by truck or van or by the supplier in some way. And so, if you think about a wheelchair or a hospital bed or oxygen, those are suppliers that are responsible for delivery and set up and come out to the beneficiary. This is an in-the-home benefit. By statute, it is in the home, and so suppliers come out to the home.

Mr. FORTENBERRY. It will take care of itself.

Mr. WILSON. Right. And I would say that for diabetic supplies we did not include storefront diabetic test strips in competitive bidding so that beneficiaries would have an opportunity to still be able to get their drugs and their diabetic supplies in the same place, community pharmacies.

Mr. FORTENBERRY. The 30 percent target of contracts to small suppliers, why don't we define a small supplier?

Mr. WILSON. It is—we worked with SBA on this. And in fact, this was recommended by this Committee, that we take a more targeted approach, in the comments to the rule, a more targeted approach in our definition of a small supplier. So rather than look at a small business, which under SBA rules at the time was $6 million, moving to $6.5 million, we relied on comments to establish a standard at $3.5 million. So about half of the SBA standard for a small business. Because we felt that was more in line with the relative size in terms of receipts, dollar receipts of this industry. And then, of course, we established the policies that I mentioned around that new definition.

Mr. FORTENBERRY. And one of the other issues regarding definition of quality is to ensure that a potential beneficiary might not have to deal with multiple locations to obtain the sets of products that they would need for various complications.

Is that a part of the quality assurance measure as well?

Mr. WILSON. Well, it is not a part of the quality standards. I think what you are referring to, sir, is how we designed the bid process, how we designed the product categories. So a supplier's bid on product categories—wheelchairs versus hospital beds—a beneficiary who needs both may have to go to two suppliers; you are absolutely correct.

The reason we did it that way was out of a concern for small suppliers. We didn't want to have the product grouping so large that a small business that only focused on one or two groups couldn't bid for this broader array of services. So it was, sort of, a balancing act between a beneficiary issue and a small-supplier issue that we dealt with through rulemaking.

Mr. FORTENBERRY. I see. All right.

Thank you, Mr. Chairman. Those are the questions I have for now.

Chairman SHULER. At this time, I would—Madam Chair, do you have any questions?

Ms. VELÁZQUEZ. Yes, I do have more.

Mr. Wilson, the Committee has analyzed the list of 320 contract suppliers announced in the first round, and we found that, in the Cincinnati competitive bidding area, 19 out of 101 contract providers across all product categories were not in that area. That is 20 percent.

In the Cleveland competitive bidding area, 27 out of 113 contract providers were not in Ohio. That is 24 percent.

But just this past Monday, Mr. Williams said that 90 percent of contract providers are in the areas where they are providing service.

Can you discuss this discrepancy?

Mr. WILSON. Well, I think we need to look at that number carefully. The thing that I will say about the 90 percent figure is this was constructed by my staff—

Ms. VELÁZQUEZ. Uh-huh.

Mr. WILSON. —and what it looks at is precisely this. It looks at suppliers that are, one, in the State, because suppliers across the State, they may not be in the CBA, the competitive bidding area, but they do business there because they have delivery arrangements there.

Ms. VELÁZQUEZ. Well—

Mr. WILSON. And, two, it excludes—

Ms. VELÁZQUEZ. So you are telling me that Mr. Williams's statement is incorrect?

Mr. WILSON. I am giving you the parameters of that statement.

Ms. VELÁZQUEZ. Yeah, but I am asking you a question. Uh-huh.

Mr. WILSON. And the second part of those parameters is it does not include diabetic supplies, which are only mail-order in this program and defined as ordered remotely. So that is a remote business. It is mail-order. You wouldn't expect to see them necessarily in the competitive bidding area.

Ms. VELÁZQUEZ. Well, I didn't make the statement. Mr. Williams made the statement. And he said clearly that 90 percent of contract providers are in the area where they are providing services. When I give you the example of Ohio with Cleveland, it is not such.

Mr. WILSON. And, again, the statement is correct with respect to the parameters that I have outlined.

Ms. VELÁZQUEZ. I asked you a question before regarding the 325 winning bidders and the fact that they will be able to subcontract. My question is, can you tell this Committee today that all the 325 winning bidders are State-licensed?

Mr. WILSON. Are licensed within the State?

Ms. VELÁZQUEZ. Yes.

Mr. WILSON. I don't know the answer to that question.

Ms. VELÁZQUEZ. But that is part of the rules of the Medicare requirements.

Mr. WILSON. I would be very happy to get back to you on that issue. I just don't know the answer to that question. It is a question that would be something I could check with the folks at CMS.

Ms. VELÁZQUEZ. Well, you have 1 week to submit in writing to this Committee what is the status of all those 325 bidders.

Mr. WILSON. I can do that.

I can tell you they are all enrolled in the Medicare program, all accredited by an accreditation organization. I just do not know the status of licensure, given there are different State licensure requirements. I am just not familiar with them.

Ms. VELÁZQUEZ. And that was not part of the requirements of the Medicare regulations at the time when they were submitting their bids?

Mr. WILSON. I think there are standards that suppliers have to meet; I know there are. They involve their enrollment. I am not familiar with every standard personally. I am very happy to get back to you within 1 week.

Ms. VELÁZQUEZ. Thank you.

Thank you, Mr. Chairman.

Chairman SHULER. Thank you, Madam Chair.

It is an honor to actually have somebody on the Committee who probably knows more about this issue than any Member of Congress. This is his profession, this is what he did before coming to serve his community in the 1st District of Tennessee. And so I yield to Mr. Davis from Tennessee.

Mr. DAVIS. Thank you, Mr. Chairman. I appreciate the opportunity. And I would like to expound a little bit on what you were saying.

And, Mr. Wilson, thank you so much for being here.

I am a conservative Republican. I think we do need to save tax dollars. So I want that on the record.

I am also a respiratory therapist by training. I also owned an HME DME company back in the 1980s and 1990s. My mother had emphysema COPD. My mother passed away. She was on home oxygen. And I can tell you, if my mother had had to depend on a supplier from a different State or a different region for her health care, my mother would have died years earlier. She would have ended up in the emergency room much more often. There would have been no way, in her chronic health condition, she would have been able to stay at home.

Now, with all that said, going back to me being a conservative Republican, would it have been in the best interests of the taxpayers of America to have had my mother either, number one, pass away years earlier, or number two, end up in the emergency room much more often, which is much more costly, or number three, ended up in a nursing home, which would have been at least 10 times more expensive than having home oxygen? So I think we have to take all of these things into consideration when we make these decisions.

I was also a surveyor for the Joint Commission on Accreditation of Healthcare Organizations. So I visited health-care DME companies all across America, and I saw some good ones; quite frankly, I saw some bad ones.

And if we are going to pass policy in Washington, I don't think we ought to be passing policy to punish good suppliers or pass policy that is going to take away services from American senior adults. I think we need to pass policy—if someone is breaking the

rule or a fraudulent actor, go after them. Throw the book at them. But don't go after the 97 percent of suppliers that are doing the right thing.

Have you done a study? Can you tell me how much 1 month on home oxygen costs? And then can you compare that to what 1 month in a hospital would cost or 1 day in a hospital would cost?

Mr. WILSON. Let me deal with the last question first. We pay about $200 a month for oxygen rental, rental of equipment. There are additional payments, I think in the area of about $70, for portable tanks. Depending upon the technology, there might be an additional add-on of $50 or so if there is certain types of new technology.

Mr. DAVIS. So about $300 a month for home oxygen?

Mr. WILSON. Probably $300 a month, maybe a little bit more.

And certainly a hospital stay, depending on the diagnosis, can be anywhere from, you know, $8,000, $20,000, $30,000 just for a couple days in the hospital.

Mr. DAVIS. Now, putting back on my conservative Republican hat, it doesn't seem like a good process for the American taxpayer. We need to look at this on several fronts: quality front, affordability front, the taxpayer front. And I just hope that we do those things.

And then, being a former joint commission surveyor, I hope that when we make these decisions and we start to look at who is going to win these competitive bids, that we use some common sense. I am hearing stories of people in Asheville, North Carolina, that need home oxygen and health care; actually their contracts are being won by companies in different States. I can tell you, when an oxygen machine goes down or a tank runs out at 2 o'clock in the morning, they have to have care.

And I don't think that many people in Congress understand that for that $300 that you said they are paid now they have to have respiratory therapists, they have to have people deliver, they have to pay the gas prices to get there. It is not just a piece of equipment that you drop off and you never see again until the patient dies. It is one of those things where you actually have to have some hands-on with the beneficiary.

So I just hope, as we are awarding these contracts, that we are looking at cost and quality.

And I yield back.

Chairman SHULER. Thank you, Mr. Davis.

At this time, I yield to Mr. Braley for his questions.

Mr. BRALEY. Thank you, Mr. Chairman.

I want to thank my friend from Tennessee for putting a compelling human face on the issues that bring us here today. I have the privilege of serving with him on the Subcommittee on Contracting and Technology, which has benefited greatly from his wisdom and personal experience.

Mr. Wilson, it seems to me that this competitive bidding process started with the fundamental premise that bigger is better. Would you agree with that?

Mr. WILSON. No, I would not agree with that. I am not sure what you mean, sir, by bigger is better.

Mr. BRALEY. Well, it seems by setting up a competitive bidding process which, in principle, is going to eliminate many of the providers from the marketplace as a natural part of the bidding process is a determination made in advance that the largest companies are going to have the best chance of satisfying the criteria that were set up.

Don't you agree with that?

Mr. WILSON. I don't. And the reason is I think what we tried to do in the rulemaking is design policies, some of which, again, we received in comments from this Committee, other Committees, and from those in the industry, to allow small businesses, small suppliers an advantage. I mentioned those in my testimony.

The result of that was 64 percent of the contracts offered going to small suppliers, meeting that $3.5 million threshold. And so I think the results there speak for themselves, sir.

Mr. BRALEY. But one of the things that concerns many of us on this Committee is the point that Mr. Fortenberry raised, and that is the issue of service to rural areas and the distance involved in providing quality and affordable care to patients who are in need of these products and services.

We have a witness who will be testifying here later from my district. She lives in Fayette County, population 22,000. Clayton County right next to it, population 22,000. Buchanan County in my district, 21,000. Delaware County, 18,000. Butler County, 15,000. Mr. Fortenberry, I am sure, has counties in his district which have lower populations than this.

And as someone who has seen what has happened as services in particular segments of business are nationalized and the deterioration in the access and quality of services in rural parts of our country, I am at a loss to understand how this competitive bidding process is going to benefit the constituents I represent in these counties.

Could you explain that to me?

Mr. WILSON. Well, I guess I would like to answer that in a couple ways.

One, under the statute, we are only tasked to implement this program in 10 and then an additional 70 metropolitan areas. And in the future we can do other areas, but we do have authority to exclude rural areas. We are only working on the metropolitan areas right now, and we are only working on round one.

In addition, the statute gave us authority to exempt low-population-density areas. So when we selected Riverside, for example, in California, we focused the competitive bidding on the city of Riverside and areas surrounding it and cut off half of the metropolitan area that was mostly desert and rural areas to the State.

So my answer to that is that we are implementing the program, we think, consistent with the law and have used our authority to exclude these low-population-density, arguably rural areas when we can.

Mr. BRALEY. But don't you see the challenge that is going to create for small-business owners? Because in States like Iowa and Nebraska, if you are going to survive as a small-business owner you are going to have to have an ability to sell into both markets, those

SMSAs as well as rural markets, in order to justify the costs of providing care in rural areas.

When you cut out bidders from having access to an area where they have lower transportation costs and higher population densities, you are automatically imposing burdens on those small-business owners that are going to make it more difficult for them to compete and obtain reimbursement under this same scheme.

Do you understand that?

Mr. WILSON. I absolutely do. And I think we do recognize that concern, absolutely. And one of the reasons that we allowed suppliers to band together and into networks was to try to overcome that concern, as well as provide other opportunities for small businesses. So, again, yes, we do.

Mr. BRALEY. And then my final question goes back to the point I made in my opening statement, and that is why it was necessary in the statute in the final rule to waive the requirements of the Federal acquisition regulations and providing no administrative or judicial review of six specific components of this process.

That seems to be fundamentally an un-American philosophy, and I would like you to explain why that is part of the bidding process.

Mr. WILSON. That waiver of judicial and administrative review was in the statute. We incorporated that as part of our regulations.

The thing that I would say is I think it is appropriate for suppliers to have a hearing or for CMS to review an issue where they have a concern.

That said, when we did disqualify a number of these bids, which is, I think, the greatest area of concern and tension on behalf of those suppliers that bid, we did allow them to come to the contractor and present their concerns. The contractor reviewed those concerns, made a recommendation to me and my staff, and we and me personally reviewed those concerns. And, in eight cases, we did overturn our contractor and allow that the bid evaluation move forward, and some of those suppliers are getting contracts.

So we tried to incorporate that oversight, that review, take responsibility for our contractor and make some mitigating changes where it was appropriate. So I agree with that philosophy.

Mr. BRALEY. Thank you.

Chairman SHULER. Thank you, Mr. Braley.

At this time, I would like to recognize Mr. Gonzalez, who is one of our great leaders here on the Small Business Committee, the one that we can rely upon, depend upon, and always ask for a lot of his advice. And at this time, Mr. Gonzalez.

Mr. GONZALEZ. Thank you very much, Mr. Chairman, and thank you for allowing me to sit in since I am not a formal member of this Subcommittee. But it is an important issue, and just about all of the other Subcommittees have had a CMS representative testify.

And I am going to make certain assumptions, and then I want to follow up on this. And it touches on some of the things that my colleagues have already touched on.

But as you make this evaluation, as you have these contractors go out there and figure what the people will be bidding on, the suppliers, the first assumption is that you do take quality of the equipment and the product into consideration. All products, all equipment are not created equal. That is going to be an assumption. So

when you go out there, there has to be certain characteristics, conditions and requirements of the particular equipment or product that you are seeking different companies to bid on. That is just an assumption, that you take that into consideration.

The second assumption is the adequacy, the efficacy part of the particular equipment or product, that it will do the job that it is intended to do. And then, lastly, that there are certain products or services, equipment that require—and I think some of my colleagues touched on—instruction, guidance, follow-up, maintenance, support, and that whoever is going to bid has the capacity, the ability to do all of that.

Those are my assumptions. Am I correct to assume all that?

Mr. WILSON. You are.

Mr. GONZALEZ. And how did you do it? Let us start off with the quality of the equipment or the product that is being submitted for bid, because all equipment is not created equally.

So I just want to know, how do you fix those parameters?

Mr. WILSON. Well, all equipment is not created equal, but the type of equipment we are dealing with, I think in all cases, thinking down the list—maybe not walker—is FDA approved. We are talking about FDA-approved products. So these are products that have been judged by the FDA and approved either through a PMA process or a—sorry—a premarket evaluation process or a 510(k) approval. That is what we are talking about.

From there, we did do a few things in the rule to ensure that suppliers provided quality product, having a transparency process so that all products are listed on the Web site, publicly available for physicians, for families, for beneficiaries; and that is part of the competition. Beneficiaries will vote with their feet and go for the best products, and so will physicians.

The other thing is an antidiscrimination clause, where a supplier can't provide one type of product or brand to their Medicare patient and another to their private care patients. So we tried to do some things to support that and go sort of beyond FDA approval.

The second thing I would say is, the—you know, the accreditation program which is an important program—on-site reviews, going out looking at the business model, the care model of suppliers—gets to many of the issues that you mentioned. So we are accredited based on quality standards that go to things like interaction with physicians by a supplier to ensure they get the right care, delivery, setup of equipment, and beneficiary education on the equipment consistent with the package insert or the guidelines. There are also special standards for important products like complex rehab mobility, complex power mobility and for oxygen, special accreditation standards on top of the basic ones.

Mr. GONZALEZ. Once you go through this preliminary process you just described, is there room for input, what I consider in the real world; people that are utilizing the equipment, utilizing companies' product, utilizing a company's service follow-up, technical advice and so on?

What I am talking about is, let's say you have the physician community saying this particular piece of equipment, even though there are four different models out there or products by different

manufacturers, this is the one that is the most efficient and effective, this is our choice.

And then, of course, you have the hospitals that they agree we get the best results with this particular equipment. Then we have patients, too, that obviously had very good results.

Is there room in this equation of yours for this type of input?

Mr. WILSON. Two things I would say about that issue.

The answer, sir, is ″yes.″ The two things I would say: One, the products we have seen—and we have looked at the products because we have asked suppliers to report what products and brands they are providing; and what we are seeing is a lot of the same national brands of wheelchairs, of oxygen equipment, diabetic supplies, et cetera. So we are seeing the same quality of products that beneficiaries are used to using.

With respect to the issue of whether a patient needs a certain, specific brand or mode of treatment and the physician says, this patient has to have that brand, there is a process that is actually outlined in the statute and then carried forward in our regulations that allows a physician to say, where it is medically necessary, the supplier has to go through a process to obtain that brand or mode of delivery for a patient.

So I think we have tried to factor that into the process.

Mr. GONZALEZ. Part of the reason I am asking these questions, we are going to have witnesses later that I believe will probably have a difference of opinion.

And my time is up. Mr. Chairman, if you will indulge me just a couple of seconds.

Chairman SHULER. I yield an additional minute.

Mr. GONZALEZ. I appreciate it.

Everything that I just talked about—because obviously I am going somewhere with this on a particular product, and that is going to be the negative pressure wound therapy, the wound VACs and such.

Are you familiar with, not necessarily controversy, but the discussion surrounding that particular type of medical equipment device, product, whatever we want to call it?

Mr. WILSON. I am, sir.

Mr. GONZALEZ. And do you feel that everything we just went over in my 5 minutes or 6 minutes now was applied, and you have reached a correct determination regarding what would be the most effective product out there that would be available under this competitive bidding scenario that you all have instituted?

I know it was first with just 10, and now we are going to go to 70 and so on areas. But do you believe you have followed that and you have come up with a good outcome?

Mr. WILSON. I absolutely believe that.

We have looked at this product very closely over the year, including encoding decisions, looking at this product relative to other products on the market in the same space, looking at the medical evidence that has been reported; and there are a number of different negative pressure wound therapy products on the market now. There are at least three, four, and we know that they are being—some by big device and drug companies that are being pro-

vided, and they will be included in this process of competitive bidding in the 10 areas.

Mr. GONZALEZ. I appreciate your answers. My fear, of course, is what is going to be available to a non-Medicare patient is a superior product that will not be available to the Medicare patient under the scheme of things, as instituted by the CMS.

I yield back. Thank you very much for your indulgence.

Chairman SHULER. Thank you, Mr. Gonzalez. Thank you.

At this time, I would like to recognize Ms. Clarke for her questions.

Ms. CLARKE. Thank you very much, Mr. Chairman. Thank you very much.

I wanted to raise some questions around beneficiaries, quite frankly. You talked about this program being prescribed specifically for metropolitan and highly dense areas. I want to know whether CMS has looked at the disruption to beneficiary access, or beneficiaries that obtain competitively bid items from suppliers that were not awarded contracts, and what the proposal is to make sure that the continuity of care is there.

Mr. WILSON. Well, that is, I think for us, moving to July 1 over the next 6 weeks, the key issue. That is where we are right now, having a ground game, having an approach to go forward and educate beneficiaries so that as of July 1, every beneficiary that needs a product will know where to go. When they get a physician, when they get a prescription from a physician or from a discharge planner, they know where to go. They know where the beneficiary needs to be sent.

That is the key issue, so we have looked at that. We have an effort under way to educate beneficiaries, educate others.

Ms. CLARKE. I am clear on that. But we are talking logistics here, and just as crucial is—our colleagues have spoken about the rural area. You are talking about densely—I am from New York City, and your agency could spend that period of time that you are talking about evaluating right now just on New York City alone, let alone all of the other metropolitan service areas around this Nation.

And you are talking about a drastic change in what people, particularly the elderly and the infirm would have to do in order to have continuity of care. That transition is critical to their survival, to the quality of health care, that they continue on in terms of being able to access the appropriate equipment. And it is a huge change in behavior for a lot of these individuals, a lot of the companies.

I wanted to raise that because I really want us to be very focused on, you know, unintended consequences here.

What percentage of beneficiaries will have to switch suppliers in this program? Do you have a percentage?

Mr. WILSON. We don't have a percentage yet. And one of the reasons is that, you know, for many of the items—I think more than half—a supplier can continue to provide services as a grandfathered supplier. So for oxygen, for example, they could continue to supply their current patients.

We don't know how many—

Ms. CLARKE. Mr. Wilson, I understand that. But it would seem to me that that would have been sort of one of the things you would have done in tandem with issuing the RFP, because this way you already know what your catchment group is and what the gaps will be.

There will be gaps particularly in highly dense populations, and there is going to be a concern about—and really a panic when people are reliant upon medical equipment for their day-to-day lives, and all of the sudden there is a switch and the educational piece does not necessarily come together in time. The next thing that is going to happen is panic, and that is going to exacerbate the health care concerns.

So it would just seem to me that that would be—we would have to multitask here.

And I am not comfortable with not knowing those percentages, so I just want to encourage you to really try to have a parallel track where that is concerned because, again, I am very concerned about the delivery systems that we have in place. We have looked at changing that delivery system in order to be more efficient, but at what cost?

There is a cost to small businesses that are no longer in the loop, that have had relationships with the clients. And there has been a delivery system. Maybe you don't believe that system was efficient enough, but this change can also mean a disruption in critical care that people need to receive.

So I think that, you know, there are some ″cart before the horse″ scenarios here that were probably unanticipated or that, for whatever reason, were not dealt with in tandem with the rules that have been promulgated and the contracting arrangements that are now being put in place.

Can you tell me what percentage of beneficiaries will have to obtain a new prescription for their competitively bid items?

Mr. WILSON. I am not sure they will need a new prescription. Many items are—

Ms. CLARKE. Are you positive? It is not about whether you think or you are sure; it is, are you positive?

You see, the thing about it is, at the end of the day, I am looking at the beneficiaries. And you may speculate today that may not be the case. What if it is? What if it is the case that people have to get new prescriptions because the distribution chain has been disrupted and reconfigured?

We are talking about densely populated areas. These people are going to rush to the emergency rooms. And in these areas they are already inundated in the emergency rooms.

So I am really glad that you are here today, because I wanted to raise these questions with you. And I know that the health care delivery system requires a response, a response before this implemented.

I hope you will get back to this committee with a lot of answers. Dedicate some staff. Let them look at this. Because we have concerns about the entire United States of America.

You have decided that the best way to be efficient here is to target metropolitan areas. Well, let's talk about the density of those areas and how we are going to effectively and efficiently use this

new paradigm that has been set up for delivery. And what is the backup plan if what you believe will happen has unintended consequences?

I yield back the rest of my time, Mr. Chairman.

Chairman SHULER. Thank you, Ms. Clarke.

I do have a follow-up question, and if any of the other members would like to have a follow-up question as well, I will offer that at this time.

Contracts were awarded. Are those contracts reassignable from the—from one company to another? If you win a contract, can you then reassign it to someone? If so, if that is the case, what actions is CMS taking to make sure they are a qualified company?

Mr. WILSON. I don't believe they are reassignable, Mr. Chairman. I think that in the course of business, a supplier could be bought. But we reserve the right to terminate a contract any time we like if we feel like the terms of the contract will not be met. And if we do that, we will withdraw the contract and we will place another contract supplier in their place. You can't just reassign that.

Chairman SHULER. So as you look at who purchases a smaller company by a larger company, are you looking at that process in every single contract?

Mr. WILSON. They are required to report to us if that is going to happen.

Chairman SHULER. Let's say a large company buys out a small company that the large company was denied. Can they assume that contract then?

Mr. WILSON. I think that, again, we have the right to not accept that.

Chairman SHULER. They were qualified the first time, though. You are saying they weren't qualified the first time they submitted the bid.

Mr. WILSON. So we have the right to review that and make a determination that we are not going to accept that.

Chairman SHULER. So it only seems rightfully so, if you denied them the first time, if they buy a company that has a contract, then they should not be—they shouldn't be able to have that contract.

Mr. WILSON. Well, if we deny them on a price issue, and that is now moot, it may not be the case. But if we denied them on another type of issue that was more of a program integrity concern or something else, that could be a concern.

Chairman SHULER. Back to the quality of care based upon the company's accreditation, a company—some of these companies were actually awarded contracts in areas which they have never serviced. So how do you look at quality of care, from the beneficiary standpoint, if they have never been in that type—you know, what gives them the qualifications that you would be able to award them with a contract if they have never been in that business?

Mr. WILSON. That is a very good question. I think what we have said is, we do understand that companies come into new areas all the time, have for years. What we have now in place is an accreditation program and financial standards to ensure that we have viable entities there for the long term to meet beneficiary needs and those that meet our quality requirements; that is, standards in

place that didn't exist before that we think give us some assurance of quality of care in viable entities.

Chairman SHULER. Ms. Clarke, do you have any follow-up?

Ms. CLARKE. Yeah, I actually do, Mr. Chairman. Thank you. And it really harkens back to a question that was raised by yourself and our chairwoman; And it has to do with the subcontracting.

What wasn't clear to me was the level of accreditation that is required for the subcontractors to maintain a certain quality of care, in that your agency has documentation that affirms their accreditation and ability to do this. It becomes even more of a concern if we have prime contractors, for lack of a better term, that don't have any experience in the industry.

What kind of liability are we taking on here if a beneficiary, as a result of us not having this information, is harmed in some way? Have you taken that into consideration? And what are you prepared to do to address this?

Mr. WILSON. Let me quickly address the premise. First of all, accreditation is new. Every single supplier that was a contract supplier is accredited and meets all of our other standards of Medicare.

The question the chairwoman raised had to do with subcontractors and when they are accredited. There is not a national accreditation requirement until September 30, 2009, because that is new. So they may not be now; they may be later.

I think what we have to look at is whether we make that a permanent requirement.

Ms. CLARKE. But there was some doubt in your response as to whether all the 325, currently who are awarded, actually have the accreditation and licensure that is required.

Mr. WILSON. No doubt in my mind on accreditation in meeting all of Medicare's enrollment standards. I am not familiar with every aspect of State licensure. It is different in each State, and I am not familiar with that particular requirement in our standards as it has to do with State licensure.

I will get back to the committee on that.

Ms. CLARKE. Yeah, I think that that is going to be important because it is part of the Medicare rule. That is critical.

And, again, I am concerned about liability. You are saying that the prime contractors, for lack of a better term, are the individuals that you are holding to this standard, but if you have a new company that has met this, it has never done this work before, and they go to a subcontractor that you may have found to be unworthy now and they are subcontracting with them, isn't that a diminishing of the quality of care for whomever they are going to be delivering these services to?

Mr. WILSON. I think we would be worried about a situation like that. I would hold the contractor accountable for the quality of the care.

Ms. CLARKE. You are going to be holding the contractor accountable. That is all well and good. But on the end of that is the beneficiary. And you won't know until something happens to that beneficiary, because we didn't take the time to do the due diligence around the subcontractors.

And I think that that is really, really important because, again, you have changed the whole paradigm here; and I think everyone in the food chain, for lack of a better term, needs to have the same level of scrutiny applied. We need to be able to affirm to the American people that we have set that standard across the board, and that different companies haven't been given a different preference in that we are not vigilant in the quality and standard in the delivery of care and supplies that maintain lives in our society.

I submit to you that that is just as important. And the owner should not only be on those companies that, for whatever reason, rose to the level where they have obtained this contract. How do you get accountability out of that?

Mr. WILSON. And I guess the thing I would say is, I don't disagree with anything that you said. But I think what I would say is that, where we are now, is in a far better place than where we were before we implemented the quality standards, accreditation and financial standards.

So we have upped the game, improved the system; and I think you are pointing out some areas that we need to look at closely as we move the system forward and see if there are other—

Ms. CLARKE. Because we left a hole; there are unintended consequences. And if we are going to move and step up our game—and there is this glaring hole there that even a layperson like me can see—then it would seem to me that those within your agency whose full-time work is to make this thing happen, would be able to see it as well.

And so it becomes almost negligent if we don't apply the same level of standard to the entire process, so that the American people can feel assured that we have put in a top-notch health care delivery system that they can rely on.

There will be a lot of trepidation out there. Like I said, you have got a huge task here. You are going to be changing this and you are going into major metropolitan areas, densely populated, a lot of health care challenges in many of the areas, a lot of people relying on these supplies and equipment.

It is going to be really critical that we have our finger on the pulse of every single part of this system; and I submit to you, Mr. Wilson, that that subcontracting piece is just as important as the 325 awardees that you have already identified.

Thank you very much, Mr. Chair.

Chairman SHULER. Thank you, Ms. Clarke.

Mr. Gonzalez.

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

First of all, Mr. Wilson, I appreciate your testimony today; and I think you have been forthright and candid. We appreciate the work of CMS. We mandate that you save money, we legislate that you save money; but the question is how you go about doing it. And sometimes I think you have to report back to us that, if we want quality care, it may be hard to save as much money as we are asking you to save.

And that is the reality of it. And whether you are a Republican or a Democrat, we don't want fat, we don't want excess spending; we want to reduce taxes, but we want a realistic assessment of

what it takes to deliver quality health care to our Medicare population and, also, Medicaid.

But I am just talking about the—the next step that is really important and what I have discovered—and I am sure that this is not going to be any different; whatever CMS does sets the baseline and the standard, and then is adopted by the private sector, the private payer.

So if you determine what is proper protocol, if you determine what is the proper equipment, if you determine what are those guidelines and restrictions and so on and what you are going to pay for, my understanding is, private sector is real happy, they adopt it and—I mean, there are tremendous consequences to what you do.

Staff always prepares a memo—and I always want to thank staff for preparing these memos; these are just incredible—and this is what it says. ″The CMS bidding process consists of three stages. The stages are fairly complex, but simply stated the process involves the following: one, a prescreening stage; two, a bid submission stage; and three, a pricing stage.″

And I am always caught up in process. I love process because the quality of the process determines the quality of the product. I am wondering, was this all done in house, or did you contract out? Because CMS does that.

I know that we have this RAC program with physicians, where private contractors go out there and try to find overpayments. And that is private-sector run; and it is a contingency fee, and that has always bothered me.

But I am just wondering—I am just assuming all this prescreening and the bidding process was conducted by in-house CMS personnel. Or was that contracted out?

Mr. WILSON. Most of the work was contracted out to a competitive bidding implementation contractor, or CBIC.

Mr. GONZALEZ. And what was the basis for payment? I mean, there is no contingency. I would imagine because they are just putting out that we can save money. But surely the incentive would be there to come back and tell you, This is the way we are going to save money. You didn't hire them to come back and tell you we can't save you any money.

But what was the contractual relationship? Was it just a straight payment for their work, or was there an incentive to say, if you come back with a 10 percent savings, then your compensation may be predicated on what you can save? Anything like that?

Mr. WILSON. Absolutely not. This program is based on a fairly well prescribed methodology for pricing bid evaluation that was put forward in a regulation through a public process with an advisory committee composed of industry, beneficiaries and practitioners and, I think, very well thought out in that regard.

But nothing like that.

Mr. GONZALEZ. All right. Well, I appreciate it very much. I yield back.

Chairman SHULER. Thank you, Mr. Gonzalez.

Mr. Wilson, thank you for your testimony. And I want to thank your staff, as well, and I hope that—I assume some of the CMS staff is here. I think it is even more important and more vital, and

I know that your time is very valuable. It is even more important that you hear the testimony from the next two panels.

We can talk about it. We have discussed it with so many of the panels, but I think it is vital that you—as many of you as can stay and listen to the testimony. So that would be very helpful.

And I think we have a work in progress, as so often we do here in Washington. Sometimes policy looks good on paper, and then when we enact it, then we have got work to do. We have got our work cut out for us.

I think, as you see, this committee has always been very bipartisan. We try to work together. And I think you have seen it from David Davis in Tennessee to Ms. Clarke in New York that we have some work to do. And the most important thing is quality of care.

So let's please take that into consideration, and I do commend you for your testimony and for your honesty. Thank you.

Mr. WILSON. Thank you, sir.

Chairman SHULER. Let's go ahead and have the second panel take their seats.

[Discussion off the record.]

Chairman SHULER. I would like to welcome the second panel to this very important hearing that we are having today. I thank you for your testimony ahead of time, and also I thank you for your commitment to whether it be your association or your own community and, most important, to the patient care.

Chairman SHULER. At this time, our next witness will be Mr. Bob Haralson, the Medical Director of the American Association of Orthopedic Surgeons, from Rosemont, Illinois. Dr. Haralson is testifying on behalf of the American Association of Orthopedic Surgeons, a group that I know all too well at times.

Dr. Haralson.

STATEMENT OF DR. ROBERT H. HARALSON, M.D., M.B.A., MEDICAL DIRECTOR, AMERICAN ASSOCIATION OF ORTHOPEDIC SURGEONS, ON BEHALF OF THE ASSOCIATION

Dr. HARALSON. Thank you, Mr. Chairman and Mr. Fortenberry and members of the committee. I am Bob Haralson. I am an orthopedic surgeon. I am here on behalf of the American Association of Orthopedic Surgeons, which represents 17,000 Board certified orthopedic surgeons.

I practiced in Knoxville, Tennessee, for 33 years and we implemented DME in all nine of our offices, and so I am very familiar with the issues regarding DME. But I would like to thank you for the opportunity to present our concerns with the many changes being implemented by law and regulation concerning DMEPOS.

We share Congress' aims at increasing the quality of patient care, eliminating fraud and abuse in the Federal health care programs and reducing the cost of delivering care to beneficiaries. And it is our pleasure to appear before you today to continue our work towards those goals.

With that said, I would like to highlight what we believe are some unintended consequences of applying rules meant to—for retail DMEPOS suppliers, to physicians and small practices across the country.

As part of providing high-quality care to our patients, it is important to note that we are talking about physicians who supply DMEPOS only to their patients, not to the general public. And because many of our physicians who provide DMEPOS are essentially small businesses and many provide those items to their patients because they are the only supplier in the rural areas, we are especially appreciative of your willingness to discuss this today.

I can take you through some of the concerns we have regarding new and revised rules pertaining the provision of DMEPOS to our patients. Specifically, I would like to address the application of DMEPOS quality standards to physician suppliers, the quality standard accreditation process for physician-suppliers and the impact of the DMEPOS competitive bidding program on physician-suppliers.

Collectively, these changes threaten to interfere with the continuity of patient care and the primacy of the patient-physician relationship and significantly increase the financial and administrative burden on many physicians participating in the Medicare program. Currently, the rules make no difference between large retail DMEPOS suppliers and physicians who are also serving as DMEPOS suppliers solely during the course of caring for their patients.

I would like to personally thank CMS staff for their willingness to work with us on how quality standards are applied to physicians who enroll as DMEPOS suppliers. However the AAOS believes that the one-size-fits-all approach to the quality of standards is not in the best interest of patients and will have an adverse impact on the patients' ability to access DMEPOS from their physicians.

We have made CMS aware of these concerns, and while staff have acknowledged the difficulties of applying quality standards to physician-suppliers, the AAOS is concerned that CMS believes it lacks authority from Congress to provide flexibility for physician-suppliers in setting quality standards. This is certainly an area where we would request the committee's assistance.

The second major topic I would bring to your attention is the burden of the quality standard accreditation process. We acknowledge and share congressional and CMS interest in assuring Medicare beneficiaries receive high-quality care, supplies and services. We are equally committed to ensuring that patients have access to the care and supplies that they need in a safe, efficient and timely manner.

Unfortunately, our members are finding it increasingly difficult to participate as DMEPOS suppliers. In most cases, orthopedic surgeons are submitting claims for a small number of DMEPOS items. However, in order to go through the accreditation process, a physician's practice will be charged approximately $3,000 per location for accreditation. We have spoken to some small practices that provide as little as $1,500 a year for DMEPOS billings.

This leads me to the specifics surrounding the competitive bidding process. Using the public commenting period, we expressed our concerns to CMS about the cost and burden associated with competitive bidding. We would like to applaud CMS for their decision to exempt physicians from having to competitively bid, particularly DME, including crutches, canes, walkers and folding man-

ual wheelchairs. We are, however, extremely dismayed regarding one of the other categories of products subject to the competitive bidding program, and that is off-the-shelf orthotics. In the final rule, CMS did create a separate exception from the competitive bidding process for off-the-shelf orthotics, but only extended the exception to occupational and physical therapists and did not include physicians.

Many patients require immediate access to these items for mobilization of injury support, facilitation of safe mobility or post-surgical recovery. It is unsafe and clinically inappropriate to delay a patient's access to items by sending a patient out of the physician's office without the necessary DMEPOS. We are hard pressed to understand why CMS did not include physicians in the exception.

Finally, I would like to leave you with a few recommendations. First, regarding quality standards and accreditation, we seek your support in recognizing that physicians are already trained to provide and administer DMEPOS to patients. We firmly believe that given the complexity of today's health environment, steps must be taken to ensure that there are not unnecessary or duplicative efforts required of program participants that would discourage patient access to care.

In terms of providing public confidence that the providers and suppliers of orthotics are trained and qualified, we believe that professional society credentialing and training processes and State regulation of practitioners already provide the necessary safeguards in this area. Therefore, while we understand the need for a process of this nature, we ask not that physicians and health care professionals be exempted from having to be accredited, but rather that they be deemed as having met requirements and accreditations once they are licensed or credentialed to practice medicine under State law. In the event that this is not possible, we ask for a delay of accreditation deadlines for new and existing suppliers so that a more coherent set of quality standards can be applied.

Lastly, with regard to the DMEPOS competitive bidding program, my recommendation is simple: Add physicians to the already existing exception for off-the-shelf orthotics. Failure to exempt physicians would cause significant access and patient safety issues.

I would like to thank you, Chairman Shuler and Ranking Member Fortenberry and members of the subcommittee, for the opportunity to speak to you.

[The prepared statement of Dr. Haralson may be found in the Appendix on page 77.]

Chairman SHULER. Dr. Haralson, thank you for your opening testimony.

At this time, I will yield to the Ranking Member, Mr. Fortenberry for his introduction of the next witness.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

I would like to thank all of the witnesses for joining us today, and at this time, I would like to introduce fellow Nebraskan, Dr. Jon Einfalt, from my district.

Jon is a pharmacist at Tom's Rexall Drug, a family-run business in West Point, Nebraska. Thank you, Jon, for coming today.

I would like to add parenthetically, Mr. Chairman, that I am also on the House Foreign Affairs Committee and, this weekend, was in the Middle East. And one of the meetings that we had was with the President of Afghanistan, President Karzai who, by the way, has visited West Point, Nebraska.

I told him how impressed the town still is with the fact that he jumped on a horse to tour one of the cattle lots, feedlots that we have there. And we were very proud that he visited. He immediately responded, how amazed and delighted he was that all of the children of the village, as he said, waved the Afghan flag as he went by.

So, Jon, thank you for joining us today. We are not only engaged in Nebraska in the critical issues of durable medical equipment, but those faced in the international affairs arena. Thank you.

STATEMENT OF DR. JON R. EINFALT, PharmD, RP, OWNER, TOM'S REXALL DRUG, ON BEHALF OF THE ASSOCIATION OF COMMUNITY PHARMACISTS

Mr. EINFALT. Thank you, Chairman Shuler and Ranking Member Fortenberry, for allowing me to share my thoughts on the CMS competitive bidding process for durable medical equipment.

My name is Dr. Jon Einfalt, and I am a pharmacist and co-owner of Tom's Rexall Drug, a small, independent, rural pharmacy in West Point, Nebraska. I am a third-generation pharmacist, and all that experience is in rural Nebraska.

Tom's Rexall Drug provides the West Point area with a wide range of pharmacy services. We have 10 employees. The building our store is located in has been an independent pharmacy for over 100 years. We have a high concentration of elderly patients, and it is higher than other parts of Nebraska.

There are approximately 23,000 independent pharmacies located across the country. Many are located in rural areas and represent the only health care available in their community. Currently, Nebraska has 19 of 93 counties without a pharmacy.

In the day-to-day care of my patients, I sell durable medical equipment. For years, my patients have depended on me to provide these products and the education necessary to use them properly and effectively.

Even before the implementation of competitive bidding, CMS controlled the reimbursement for these items. In fact, the reimbursement for diabetic testing supplies has not changed for many years. In addition, CMS has greatly curtailed the ability of the independent pharmacist to provide some of these supplies to patients by setting reimbursement rates well below the acquisition costs of the supplies.

Competitive bidding was introduced by CMS as a tool to control costs. I believe the rules and regulations CMS has implemented with this program will eventually have the exact opposite effect. Competitive bidding and accreditation will eliminate rural independent pharmacies and other small suppliers from the program. Rural jobs will be lost; patient access to health care will be limited.

Access is not just a rural problem. Patients will stop using their durable medical equipment, hospital long term care visits will increase, and the small savings garnered in the first few years of the

competitive bidding program will quickly be lost due to increased utilization of these higher-cost health care facilities.

I can think of several instances like this involving my patients just in the last year. Let's look at blood glucose testing strips, just because they are such an important part of treating my patients, the diabetics. Although exempt from bidding right now in the competitive bidding process, they will fall under the accreditation standard that starts September 30, 2009.

Blood glucose testing is a relatively simple process and modern equipment is fairly user friendly. However, seldom does a week go by that we aren't helping a patient deal with a blood glucose testing issue. All these contacts require face-to-face interaction and hands-on equipment. I cannot remember the last time I was able to resolve one of these issues over the telephone.

Some of these patients receive their supplies through the mail, so obviously the mail order supplier wasn't able to resolve the issue. Pharmacists routinely provide this type of valuable consultation, often at little or no cost to the patient. That will be difficult when we are no longer around.

The costs and time and money to implement competitive bidding and accreditation are prohibitive for small independent pharmacies. Current estimates to comply and participate are estimated to be $8,000 to $20,000 and 200-plus hours over a 6-month period of time.

Most rural independent pharmacies are single owner operations. I don't know how they are going to find time to prepare for and implement accreditation. With the cost to participate exceeding the profits from DME sales, you can understand that I will not be seeking accreditation or selling any durable medical equipment.

There is, however, a more ominous and perhaps catastrophic problem looming here. If CMS requires accreditation to participate in Medicare Part B, then the next contract I have to sign with the pharmaceutical benefit managers to fill prescriptions will require accreditation. Ninety-three percent of the prescriptions I fill are governed by a pharmacy benefit manager contract. Say goodbye to Tom's Rexall Drug.

Pharmacies in Nebraska are licensed and inspected by the State of Nebraska on an annual basis. Pharmacists are also licensed by the State. Both are governed by a comprehensive set of rules and regulations overseen by the Nebraska Department of Health and the Nebraska Board of Pharmacy. I do not need Federal accreditation to practice pharmacy or sell durable medical equipment. I could negotiate that section out of a future contract, but without Congress negotiating capabilities to small pharmacies by passing legislation like H.R. 971, my ability to negotiate fair contracts with giant PBMs is nonexistent.

So where does this leave the patients, your constituents? A misguided plan to produce some short-term savings and DME costs has suddenly changed into a plan that has decimated the access to quality health care for rural Americans and increased the overall health care costs for the government.

A mailbox is not a pharmacy. If a patient needs an antibiotic, pain medication, insulin, asthma medication or even a blood glucose testing strip, they can't wait 3 to 10 days to get it in the mail.

That means a long drive or doing without. That certainly does not provide an improved quality of life, and in some cases, it will mean something much worse.

Independent pharmacies are under the gun and need the help of Congress to fix this mess with competitive bidding for durable medical equipment. The results of the first round of competitive bidding are due to be implemented July 1, 2008. The drop-dead date for accreditation is September 30, 2009. Early statistics from the first round of competitive bidding show the scenario I have outlined is already under way.

There is little or no cost to the government to fix these problems. The government already controls the cost of durable medical equipment.

Thanks for inviting me to participate in your discussions.

[The prepared statement of Mr. Einfalt may be found in the Appendix on page 89.]

Chairman SHULER. Dr. Einfalt, thank you for your testimony.

At this time I yield to Mr. Gonzalez for our next witness.

Mr. GONZALEZ. Thank you very much, Mr. Chairman. I appreciate it.

It is my privilege to introduce Mr. Linwood Staub, who is President of Global VAC Therapy for Kinetic Concepts, Inc., which is headquartered in my hometown of San Antonio, Texas. KCI is a global medical technology company that develops and markets advanced therapeutic systems.

Mr. Staub has over 20 years of global experience in the medical device space. He is here, though, testifying on behalf of the Advanced Medical Technology Association. AdvaMed represents over 1,600 of the world's leading medical technology innovators, who manufacture over 90 percent of the medical devices, diagnostic products, medical information systems purchased annually in this country.

And again, welcome, Mr. Staub.

Thank you, Mr. Chairman. I yield back.

Chairman SHULER. Thank you, Mr. Gonzalez.

STATEMENT OF MR. LINWOOD STAUB, PRESIDENT, GLOBAL VAC THERAPY, KINETIC CONCEPTS, INC., ON BEHALF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

Mr. STAUB. Thank you, Mr. Chairman and members of the committee. Thank you for holding this hearing.

I am here today on behalf of AdvaMed, the Advanced Medical Technology Association. Seventy percent of our members are relatively small companies with sales of less than $30 million a year.

The company I work for, KCI, is a medium-sized company today, but it started out as small, family-owned business 30 years ago, so we understand the role that small, innovative businesses play in driving progress.

Our message today is very simple. Advanced medical technologies is a smart investment for patients and taxpayers alike. Medical innovation saves lives, it improves patients' health, and in

doing so, it very often saves money—for example, by allowing patients to be at home as opposed to being in the hospital.

Whereas doctors like to say, the most expensive equipment is the one that doesn't work, that is why we are concerned about the design and implementation of CMS's competitive bidding program. Specifically, we have three concerns relating to product interchangeability, cost savings and supplier capability issues.

Regarding interchangeability, as you know, CMS has chosen 10 specific product categories for this program I want to share with you. Two of these are walkers and negative pressure wound therapy devices, which are depicted here on the slide at the very back of your packet. Some of you may have seen that.

Competitive bidding treats both of these product categories the same way, yet obviously they are very different. One product is a simple, functional device that helps you walk; hence, the name ″walker.″ It is pretty straightforward.

The other product category is negative pressure wound therapy, a category created by CMS that includes CMS's VAC therapy. VAC therapy is a complex, sophisticated, therapeutic system that is used to treat some of the most severe and hard-to-heal wounds, often in highly compromised patients.

So, for example, a typical patient who relies on this type of treatment is a diabetic who has co-morbidities such as obesity and hypertension and may be at risk of an amputation due to poor blood circulation in the arms and legs. VAC therapy reduces swelling, prepares the tissue for healing and removes toxic fluids. So, as you can imagine, this is a technology that significantly reduces healing times, reduces infection rates, prevents amputations and shortens or eliminates hospital stays.

Basically, the VAC has proven to save lives, limbs and money, yet starting on July 1st, because of a flawed competitive bidding program, Medicare will deny access to this therapy for elderly, disabled Americans living in these communities.

Now, this loss of access wouldn't be so bad if all offerings in CMS's MPWT category were interchangeable, like walkers, but that is not the case. VAC therapy is unique and not clinically comparable with other products. In fact, only VAC has scientific studies to prove that it produces the positive effects that I described a moment ago.

We wheeled in some of the paper that the clinical studies, the peer reviewed journals, the appointments in different medical books. It took quite a job to get that in. You will see it on the table behind me. But VAC therapy has the largest body of clinical evidence in virtually any wound care product; and it is why VAC therapy is the only product cleared by the FDA specifically for use in the home, and it is why our military forces in Iraq use the VAC exclusively for the severe, complicated wounds that they treat every day.

Physicians and medical societies, including two of the Nation's largest wound care associations, told CMS that products in the MPWT categories are not clinically equivalent and that the category shouldn't be competitively bid. But the Agency didn't listen.

Our second concern has to do with the claimed cost savings of the program. CMS estimates competitive bidding will save 20 per-

cent in all product categories on average, but the estimate only looks at line-item prices. As suggested earlier, you also need to look at outcomes and total costs to determine the true value. Unfortunately, Medicare officials only plan to look at line-item price savings.

Here again, the VAC provides a good example of why this is pennywise and pound foolish. A study of Medicare patients treated with VAC therapy in the home found that patients had lower rates of hospitalization, lower need for emergency room care, as well as less pain and a higher degree of mobility. And when compared with patients who were not treated with the VAC, patients treated with the VAC at home had average cost savings between $3,600 and $12,000 per patient. Again, those savings were not factored in.

Our third concern has to do with the clinical support. Patients using therapeutic equipment require training to ensure that the products are used safely and effectively. They and their caregivers also need access to clinical and technical support 24 hours a day, 7 days a week, in case complications arise. Without this, patients could be jeopardized.

Many MPWT contract suppliers appear to lack sufficient capabilities to provide an acceptable level of patient support. We know many of them failed this test because a number of them contacted KCI, inquiring whether they could obtain VAC supplies from us and revealing that they had no experience with this therapeutic category, no supply of product, no guaranteed access to supply and no clinical or customer support capabilities specific to the therapeutic option.

So, in conclusion, we believe competitive bidding as designed and implemented by CMS suffers from serious flaws that should be addressed before the program goes forward.

And, finally, in sophisticated product categories such as this, we believe that CMS is fooling itself if it believes that low bid prices will reap lower costs. Just the opposite; there will be costs. Those costs won't come in dollars, but rather in lost limbs and in quality of life.

And in the long run, Mr. Chairman, members of the committee, we feel superior outcomes, not price alone, will save money.

[The prepared statement of Mr. Staub may be found in the Appendix on page 96.]

Chairman SHULER. Thank you.

Our next witness is Mr. Casey Hite. Mr. Casey Hite is Vice President and co-owner of Aeroflow Healthcare in Asheville, North Carolina. He is testifying on behalf of AAHomecare and the North Carolina Association of Medical Equipment Services.

Casey, you have 5 minutes.

STATEMENT OF MR. CASEY HITE, VICE PRESIDENT, AEROFLOW HEALTHCARE, ON BEHALF OF AAHOMECARE AND THE NORTH CAROLINA ASSOCIATION OF MEDICAL EQUIPMENT SERVICES

Mr. HITE. Thank you, Mr. Chairman, and distinguished members of the subcommittee. My name is Casey Hite, and I am a small

business owner and vice president of Aeroflow Healthcare, a small home medical equipment located in Asheville, North Carolina.

Aeroflow Healthcare is a company that my brother and I founded in 2001. We provide oxygen and mobility equipment and services to approximately 13,000 active patients in North Carolina, South Carolina and Tennessee.

We decided to enter this industry after visiting our grandmother, who was slowly dying from chronic heart failure in a local nursing home. The nursing home provided her with oxygen from a dilapidated oxygen concentrator which broke down frequently. This gave her severe anxiety about the possibility of suffocating in her sleep. As I am sure as I can tell you, that is a scary feeling. At that time, the only home medical equipment providers in the area were large corporations that were based in Florida, or as far away as California. We believed there had to be a better way.

I appreciate this opportunity to testify before you today, on behalf of the North Carolina Association of Medical Equipment Services, the American Association for Homecare and small home medical equipment providers nationwide.

Our company is scheduled to be in Round Two of the program bidding. I have heard and seen in detail Round One problems that have plagued this high-profile program. I am well aware of the program's anticipated effects on both Medicare beneficiaries and suppliers. The Medicare bidding program is poorly conceived and fundamentally flawed. This program is showing many of the serious breakdowns that the American Association for Homecare predicted, based on the failure of CMS to recognize and account for the way that home medical equipment is provided to Medicare beneficiaries.

The current bidding program will literally drive thousands of qualified home medical equipment 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 of qualified homecare providers that submitted bids were disqualified in the first round of bidding. Two-thirds. That is a huge amount. That dramatic reduction in the number of homecare providers will result in reduced access and quality of service that we currently provide to beneficiaries.

HME providers are overwhelmingly small to mid-sized practices that typically receive about 40 to 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.

We have been using this term ″competitive bidding″ all day, but the term ″competitive bidding″ is very misleading because CMS is radically reducing the number of suppliers that compete in a given area, resulting in market concentration rather than a competitive marketplace. 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 18 million, or about half 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, 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.

Homecare providers, like my company, are on the frontline in caring for Medicare beneficiaries. Outside of their families, we are the first person they call. If beneficiaries are not caring for themselves adequately, we are the ones who notify their family members and their physicians. This flawed bidding program will cause major disruption in service to these beneficiaries across the country. Beneficiaries have three choices. They can choose to enter a hospital, a nursing institution, or stay at home. The vast majority of beneficiaries choose to stay home. Homecare is not only the preferred choice for the patient but it is also the most cost-effective health care solution.

The Medicare bidding program is expected to immediately impact more than 4,500 home medical equipment companies in the first 10 metropolitan statistical areas.

We believe that the Medicare bidding program will radically change the HME marketplace and dismantle the nation's home medical infrastructure, if implemented in its current form. CMS will selectively contract with approximately 300 unique suppliers in the first 10 metropolitan areas under the program. CMS' own statistics have shown approximately 4,500 unique companies reside in these 10 bidding areas. So essentially this would indicate that CMS intends to contract with approximately 7 percent of the existing home medical equipment companies. Even if we only account for the unique companies that took part in the program, which was 1,005 companies, CMS is still threatening the financial viability of 70 percent of otherwise qualified and accredited suppliers in the current homecare marketplace.

Homecare has 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, the 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.

Due to the flaws, errors, and questions that have plagued Round One, and will certainly carry through to Round Two, we urge Congress to delay the implementation of this bidding program. We support 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 Subcommittee and other Members of Congress to address these complex challenges and ensure the provision of cost-effective and quality home care to deserving Medicare beneficiaries.

[The prepared statement of Mr. Hite may be found in the Appendix on page 116.]

Chairman SHULER. Thank you, Mr. Hite.

At this time I would like to introduce Mr. Heath Sutton, president and founder of Mountaineer Oxygen Services in Waynesville, North Carolina. Mr. Sutton is testifying on behalf of North Carolina Association for Medical Equipment Services.

Mr. Sutton, you have 5 minutes for your testimony.

STATEMENT OF MR. HEATH SUTTON, OWNER, MOUNTAINEER OXYGEN SERVICES, ON BELAHF OF THE NORTH CAROLINA ASSOCIATION OF MEDICAL EQUIPMENT SERVICES

Mr. SUTTON. Thank you, Mr. Chairman and distinguished members of the House Small Business Committee for the opportunity to share my story. I am a private registered respiratory therapist of 13 years. My wife and I started our company in Waynesville, North Carolina, years ago with one goal in mind, to better serve the needs of home medical equipment patients in the western counties of North Carolina.

Many patients and doctors in our area were experiencing serious difficulties in locating even adequate homecare for oxygen and sleep disorder needs, so we began our company with the motto ″Treating Patients Like Family,″ a motto which remains on our homecare truck today. By very hard work and frugal management, we have built a business in a small town area that serves over 400 home oxygen patients and 500 CPAP patients (patients with sleep disorders) with the highest quality homecare at a very reasonable cost to both insurers and to patients.

The original intent of competitive bidding was to control the increasing costs of Medicare and was mandated by Congress. As providers, we heard the call and supported the efforts as concerned citizens who wished to make government-insured care more economical. However, the results of the initial phase of the program have clearly shown that this program cannot ensure access to care or quality care, nor will it lower costs.

Implementation of Round One will create access issues and make quality care more difficult to provide. The Center for Medicare and Medicate Services is excluding almost two of every three qualified and accredited bidders with no specific information as to why, and is confirming their reliance on less than 10 percent of current suppliers to provide service to the entire 10 Metropolitan Statistical Areas (MSA) in the first round. We are certain that such a limited list of suppliers will not allow us to properly service the needs of patient markets.

By mandating that even noncontracted suppliers be reimbursed at contract pricing beginning January 1st, 2009, all who serve this market understand that lower pricing will lead to lower quality equipment. I understand from a small business perspective the desire to submit a bid in the competitive bidding program in order to try to protect some level of margin to make the business they own sustain itself and be profitable. However, thousands of small businesses will quickly fail because they simply cannot afford to stay in business, since the bidding program's median bid pulled them below what they can afford to stay in business.

Furthermore, there is no requirement for subcontractors to be accredited. Those few providers who received contracts will not be able to fully serve their markets without subcontracting. With two entities seeking margin through bid processes, quality equipment will be quickly replaced by lower quality product, and we will soon find ourselves in a market no longer known as durable. Disruption

in both quality and availability will most assuredly follow, because price is most important in the economic equation.

The large majority of beneficiaries of homecare have chosen their home providers from those available locally, most with the assistance of their physician. Now, this new program will force many, possibly most, to switch to new providers. Estimates are that literally hundreds of thousands of patients may face service disruption as a small number of new CMS-mandated providers scramble to find a way to serve these new homecare patients. Is this the very best method to assure our elderly we have their best interests at heart? These citizens are generally being well-served now, and the ultimate question rests with whether they will continue to be well-served by a ″lower priced-dictated″ marketplace. We also know that some suppliers who won contracts did so for products they have never provided. How can this process be seen as either fair or ethical under these conditions?

My company currently serves an elderly patient with severe chronic lung disease and chronic hypercapnea. She just happens to be the very first oxygen patient that Mountaineer Oxygen Services set up on home oxygen in October 2003. She lives alone and has no family and is stricken with arthritic hands. At least once a week, in a panic, she calls our on-call service between 9 and 10 p.m. on her way to bed because she cannot attach her water bottle to her oxygen machine correctly. For the past 4 years, our on-call person has received a weekly call from this patient and drives out to assist her. Several times, however, she has panicked, causing her to be unable to dial our number, and she calls 911. This patient will suffer emotional stress if we lose the bid in Round Two, not to mention the problems she will encounter if the Round Two contract winners are over 100 to 200 miles away. She relies on us to care for her needs.

As a homecare professional, I believe fundamentally that the system, as it is currently designed, is fatally flawed and will result in large-scale discord in the market structure for both providers and, much more importantly, patients, who are indeed members of our community and families, and should be treated as such.

Any system which disqualifies almost two of every three qualified providers should be questioned as to its validity and serviceability. We strongly implore you to reconsider competitive bidding. This program is flawed, and we ask that you stop it in its tracks and delay it before large-scale damage is done to our elderly citizens. There are much better ways to derive excellent homecare at lower costs and those of us who have spent our lives in this market stand ready to help you establish them.

We sincerely hope you will listen to our pleas and serve as our champions. You, as our representatives, can change this course and keep it from ruining our businesses and negatively impacting elderly Medicare beneficiaries. Thank you for your time.

[The prepared statement of Mr. Sutton may be found in the Appendix on page 126.]

Chairman SHULER. Thank you, Mr. Sutton, for your testimony and the panel's testimony.

At this time, I am going to yield my questions for later, and I will yield to the ranking member, Mr. Fortenberry, for his questions.

Mr. FORTENBERRY. Thank you, Mr. Chairman, for indulging me.

Dr. Haralson, I am glad we changed your sign. We needed to get the title right. Actually, I am going to direct my questions to Dr. Einfalt, but any of you, if you are willing to provide an insight, I would be happy to hear that as well.

You mentioned two aspects of this issue that I want to unpack a little further. H.R. 971, which would allow small independent pharmacies or suppliers to band together to basically compete for these contracts, is a bill that I am a cosponsor of. Let's talk about the potential impact that could have in addressing some of the issues that you all raise.

Secondly, you talked about the cost of accreditation being between $8,000 to $20,000. I am assuming there is no process currently at the Federal level to accept State accreditation, which would allow for waiving the Federal accreditation process. In other words, if a State meets the Federal requirements, you are certified by the State, then that would be acceptable at the Federal level if I am understanding this correctly. That might be a way in which we could address that particular issue of this. But I wanted to hear your comments on it, as well as anyone else who might have insight into this.

Mr. EINFALT. Currently what you are speaking of, there is no plan that I know of to allow States to certify and then thereby qualify them for CMS or to participate then at that point. I do know that hospitals in the State of Nebraska can utilize the Department of Health to acquire accreditation or certification, and then that certification can be passed on so that they can serve Medicare beneficiaries. So that does exist. So if there is a route for doing that certainly with pharmacies, that would be a possibility, because I don't believe there is a State around that doesn't license their pharmacies and also license their pharmacists. I think that is all in place in each of the individual States to take care of that.

Mr. FORTENBERRY. Are those accreditation standards fairly uniform across the country, or do they vary greatly do you know?

Mr. EINFALT. I wouldn't know. I would suspect there is some variation just from what I know of pharmacy law from a couple different States.

Mr. FORTENBERRY. And there might not be exact applicability in terms of being a part of the approved for bidding process, but nonetheless that might be something that could be examined to see if there is reasonable applicability given a State licensure, meaning you set up certain quality standards that would then apply for your Federal program.

Mr. EINFALT. I believe that would be something to look at, yeah.

Mr. FORTENBERRY. The second issue regarding the ability to cooperate with other independent pharmacies or providers in order to be placed in a better competitive bidding position, would that approach potentially allow for greater flexibility or put smaller independent pharmacies as well as suppliers in a greater competitive position?

Mr. EINFALT. Listening to the CMS testimony earlier, I believe that already exists, the ability to band together to submit a bid in the DME area. My concern with H.R. 971, and the reason H.R. 971 came into being or was proposed, deals with what Mr. Gonzalez was speaking to earlier. And that is, anything that the Federal Government does in implementing accreditation or standards immediately flows to the private sector. And that is what is going to have a huge impact on rural pharmacies, particularly in Nebraska, is their inability to deal with the private sector and the pharmacy benefit managers.

Mr. FORTENBERRY. So this is more of a reimbursement issue with private insurance.

Mr. EINFALT. Well, the impact is going to have there because those standards that are taken from the Federal level into the private sector, they are going to just say you have to be accredited by CMS in order to participate now in Medicare part D, and probably then all the rest of the commercial contracts that we have; 93 percent of our business is governed by those pharmacy benefit managers. So if they do that, I am done. I don't have accreditation with CMS. I don't plan to go after it. We can probably survive without—it is a smaller part of our business, and we will figure out a way to try to get around that and not sell DME. But the bigger problem is that now that standard is in the prescription arena. And when that comes in, we are done. We are gone. There is no negotiating. The pharmacy benefit managers come in and tell you what is going to happen. And we are done at that point. And that is where the problem really gets serious in Nebraska as far as access.

Mr. FORTENBERRY. The two issues are unrelated on the surface, but after implementation, they would be inextricably intertwined.

Mr. EINFALT. That is correct.

Mr. FORTENBERRY. Anybody else have input on that particular issue?

Okay.

Thank you, Mr. Chairman.

Chairman SHULER. Just as a follow-up to Mr. Fortenberry's question, so if you decide not to participate, then what is going to happen to the patients in that rural community? I mean, what is going to happen, as far as their access?

Mr. EINFALT. There is a small chain, a regional chain that has a location in West Point. So I would suspect that it will be channeled, that business will be channeled to that business, or Wilfred Brimley will come in and pick up the pieces and sell test strips to all the guys that couldn't get them locally.

Chairman SHULER. And you service how many communities?

Mr. EINFALT. We just have a store in West Point. But our service area encompasses probably, depending upon which direction you go from West Point, anywhere from 10 to 20 miles out from West Point.

Chairman SHULER. So there are going to be a lot of people impacted based upon—and they are not going to have much of a choice.

Mr. EINFALT. There will be no choice, basically. It will just happen. And we hate to do that. It has happened to us in other areas of the DME. We try to help the patients. As long as we are there,

we are going to help them. In my testimony, I brought in the part about they need help with dealing with the equipment that they can't get taken care of by mail order or some other supplier. As long as we are there, we do that. We don't charge for it. Doesn't matter where you got those strips from, doesn't matter—you got a problem, we are going to help you out with it. And we will continue to do that as long as we are there.

Chairman SHULER. Very good.

Dr. Haralson, according to your testimony, physicians' practices will be charged as much as $3,000 per location to be accredited by CMS. What do you believe is going to be the long-term effects from the pharmacist services to the Medicare beneficiaries.

Dr. HARALSON. Well, first of all, the regulations are you have to have a DMEPOS number, a unique DMEPOS number for each address. So in our situation, for instance, we had nine offices, so we had to have nine separate DMEPOS numbers, which means we are going to have nine separate accreditations. And it is $3,000 apiece. So we had technically a large, 37-physician practice. We operate in four what we call care centers. And my little care center in Maryville, Tennessee, was only four physicians. So that group of physicians probably are not going to be able to afford to provide DME from their offices.

Chairman SHULER. And once again, who—the patient care, I mean, who do they fall to?

Dr. HARALSON. Well, they go to whoever supplies them. Some of the drugstores have some of the smaller items. They don't have the bigger items. The most common scenario is the boot walker. The boot walker has revolutionized the way we treat ankle and foot injuries. Used to be, you had to have a cast. I am not sure which one you had.

Chairman SHULER. I had the boot walker, DeRoyal Industries, yes, 6 months on that.

Dr. HARALSON. The neat thing about the boot walker is you can take it off. If you have an ankle fracture that you have operated on, you would like to inspect the wound. You can inspect the wound one of two ways. You can take the cast off, which means you have to put another one, or you can cut a window in the cast, which means that's the only place that swelling can occur. And that is detrimental to the wound. The nice thing about the boot walker is that you can take it off, the patient can exercise nonambulatory and can care for the wound and wash the extremity. Those high end things like that are usually not available in the common drugstore.

Chairman SHULER. And washing being a very important role.

Dr. HARALSON. Keeps it from smelling, yes, a real problem. If you really want to see something, you go swim in the ocean in one of these waterproof casts. I would suggest you not try that. But anyway, those high-end DME products are not available in the drugstores. And they need to be adjusted, which is not available in the routine drugstore. So I think, in those situations, in my little town, they will have to go to Knoxville.

Chairman SHULER. So they will have to travel.

Dr. HARALSON. Yes, sir.

Chairman SHULER. How will the quality of care be impacted if you are prohibited from providing off-the-shelf orthotics?

Dr. HARALSON. You know, Mr. Shuler, that is an extremely important question. As you are probably aware, CMS as well as all the medical societies are really getting involved in evidence-based quality medicine. And our fuss with some of the payers is that you cannot look at costs without looking at quality. I can reduce the cost by providing sorry medicine. Most of the DME suppliers, the manufacturers, have at least two and three, and usually three, levels of quality. They have a cheap one, which is usually made out of the country because they have a competitive bidding program with the hospitals, and the hospitals take the cheapest. They are not worried about quality. So I think that if we implement this as it is suggested, that the quality really is going to take a hit. And we just insist that if you are going to measure cost, you have to include a measure of quality along with that.

Chairman SHULER. So if you are taking one of the lesser products, then basically the long-term care could be compounded over the time of the patient's life.

Dr. HARALSON. Absolutely. And the second thing about the poor quality is they wear out. And so, frequently, you have to replace them. If you are in a boot walker for 6 months and you had low quality, you are going to have three or four of those things.

Chairman SHULER. Oh, yeah. I had good quality and had several during that time period.

Dr. HARALSON. Great.

Chairman SHULER. Yes, sir.

To Mr. Hite, kind of give me an overview of—you know, they talked about during the competitive bidding process that in Charlotte, for instance, someone in Texas won a bid in Charlotte that was not skilled or had any expertise in providing care in that particular field. So let's say that they were in the electric mobile devices, and they wanted to go to oxygen, providing oxygen to our seniors in our community. I mean, what all are they going to have to go through and what concerns do you have in your business?

Mr. HITE. They are going to have to go through a lot. When I saw the list of winning bidders, I was actually shocked to see that there were providers there that had won bids in categories that they had never provided before. Now, we talked about accreditation. Accreditation, at least to my knowledge, even though we are an accredited company, it doesn't necessarily address the products that you are providing. It addresses your general infrastructure and, you know, that you have the right policies and procedures in place. So how CMS is going to look at quality when there is no track record is absolutely beyond me. I don't understand how it can happen.

Chairman SHULER. So, in fact, maybe a company in Dallas, or any part of the United States, could win a contract in Asheville, and next thing you know, you have lost your entire company that you and your brother have built from scratch based on looking at the lack of quality from your grandmother. So they could, in a sense, basically take out your entire company based upon one bid process.

Mr. HITE. Yeah, they certainly could. You know, and I think the company might—a company like this might be based, I want to be as accurate as possible, a company might be based like somewhere in Texas or California, and they might have a distribution center, a quickly opened distribution center in a place like Asheville. But with no track record in supplying a particular bid group, you know, it would take me an hour to describe how difficult that would be. I am shocked if somebody had the courage to bid on something that they had never done because you have to build—it takes time to build infrastructure. And the infrastructure it takes to support a large group of oxygen patients is huge. There are a lot of details involved in it.

Chairman SHULER. Mr. Staub, do you think the way that CMS has structured the product categories would serve a significant disincentive to small firms conducting research and development in new medical technologies?

Mr. STAUB. Well, I think that it probably goes back to some of the comments earlier on around, if we are really paying for low bid, right, we are paying for the lowest price. We are not paying for an outcome. In many cases, there is not even really good clinical data to support the efficacy of that product. As Mr. Wilson said earlier on, some of those products are 510(k) approved, which means that they just need to prove that they function. They don't have clinical studies behind them to show that they are efficacious or that they are clinically capable. So I think what happens is you end up getting a low price issue so, you know, the companies now try to, instead of developing new technology that is moving us forward in health care, you are going to develop very, very inexpensive products that we can deliver for less than anyone else but don't have good long-term clinical outcomes. And I think that is the direction the free market economy will take you at that point in time.

Chairman SHULER. What impact do you see or foresee CMS's program having on the technology innovation in medicine?

Mr. STAUB. You know, I think that is probably one of the most critical aspects. And we look at it in pharmaceutical and medical devices alike. It is very expensive in today's day and time to develop products and do the appropriate clinical studies and trials that are required to get a product on the market and make certain that they are moving health care forward. I think again when you shut down some of these small companies—as we said, ours was a small start-up from Dr. Jim Leininger, an ER physician, 30 years ago, and it is now a $1.5 billion company, so I think some of these startups won't have the opportunity really to get their feet off—or get off the ground. And that is very unfortunate in this environment.

Chairman SHULER. Mr. Sutton, you were telling me that you had beneficiaries who would call you at 1 o'clock in the morning. Why do you service them? Why don't you just tell them to call 911?

Mr. SUTTON. Well, Congressman Shuler, thank you for the question. You know, our business is 24/7, 365, and oxygen is vital for folks that are chronically, you know, hypoxic or have low oxygen in their blood. So, that is our job, and it is service-based. And we are on call, and that is what we signed up to do. And so that is why we are in the business we are in.

And what frustrates me, an example I would like to elaborate a little bit on, you know, is skilled facilities in our area in western North Carolina frequently have contracts with companies in Virginia and Tennessee and different areas. And we routinely get calls from these facilities that say, you know, this patient is qualified for oxygen. They have moved into our skilled facility and need a continuous positive airway pressure machine for sleep apnea. And the company that we contracted with, it is going to take 2 or 3 days to get the equipment. That is the comment we get from them, and so they want to pay us for a couple of days of service. And of course, we graciously go and help them out because we have to help patients, and that is what we signed up to do, even though we don't have that contract. But those are instances where those folks, if they don't get the care they need, 2 or 3 nights without a sleep apnea machine, they could have a stroke, you know, and a week extended stay in a hospital. Patients that can't get oxygen on time, if we don't take those calls at 1 or 2 o'clock in the morning and the patients are elderly, they live at home alone; they can't change a tank with the power out because they don't have the strength to do it; so if we don't make that visit out there to either change the tank or help that patient, they call 911. And that costs patients who are on Medicare more than $4,500 for one day in the hospital. The patients spend money in the hospital and make frequent visits to physicians' offices. So, you know, those are some unintended consequences that, you know, I request that you folks really look at and pay attention to. And I urge CMS to not just assume that, you know, we may save 26 percent up front, but what is going to happen a month into the program with these folks with disruption in service? The unintended consequences I can't implore enough on you to research before it happens.

Chairman SHULER. And I am sure you get paid extra after hours, after 10 o'clock at night, you get paid extra.

Mr. SUTTON. You know, Congressman Shuler, I think that is an interesting question, in that, earlier, the gentleman from CMS said that we get approximately $300 a month. And it is somewhere around $239 to be exact. And that is if you don't get a call from the patient or you don't have to deliver supplies or you don't have to go out there to see an elderly patient with chronic lung disease that has a lot of anxiety.

Chairman SHULER. So do you get paid more every time you service?

Mr. SUTTON. No, those are free visits.

Chairman SHULER. Those are free visits to you.

Mr. SUTTON. Gas is now $4 a gallon in rural Waynesville, North Carolina. So besides my cost of my driver, my technician and the time away that he could be doing other things, we are there. And that is not included in the costs.

Chairman SHULER. What is the distance between your Waynesville location and the largest, the longest distance you have to travel to service a patient?

Mr. SUTTON. We serve Haywood County west all the way to the line, which is the Robbinsville, Murphy area, Graham County.

Chairman SHULER. So 2 hours?

Mr. SUTTON. Two, two and a half hours. And it is not like interstate, a major interstate highway, Congressman Shuler, you know that, as we drive through Swain County. It is—

Chairman SHULER. We are working on that.

Mr. SUTTON. —winding roads. So it is a lot of cost. And those are things that, again, I implore CMS to consider that.

And you know, I am in Waynesville, North Carolina, and Asheville is, you know, 25 miles from my area. So I am going to assume that my ZIP codes will be included. And that has not been, you know, released yet.

Chairman SHULER. Mr. Hite, how far is your furthest area? Or would you like to comment based upon the question?

Mr. HITE. Very similar to Heath's situation. We have patients that far away. Now, obviously it is discretionary. We could, you know, choose not to accept a patient that lives long distances. But we often do, because it is a physician's choice. Physicians are referring the patient to us for a reason. You know, it ultimately comes down to the patient, but the physician is saying, hey, this is who you need to deal with because they provide this specific product, and it is going to improve your life. So, in those cases, we accept patients from long distances and travel those long distances.

And to Heath's point, you know, you are not just paying $4 a gallon in gas, you are also paying overtime to an employee to go out in the middle of the night. We will continue doing that. You know, it is just the ethical thing to do. I don't know whether it will drive us out of business. It might under the new reimbursement schedule, but it is what is right.

Mr. EINFALT. Following up on your original question, why do we do that, in rural America, that customer is not only your patient; you live with him. You live with his family. You have to face him every day. So every decision you make, you have to deal with the consequences of that decision on a daily basis, good or bad.

Chairman SHULER. Absolutely. I commend all of you for that.

At this time, Mr. Gonzalez, do you have any questions?

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

I am going to try to go quickly. I think we are going to have a series of votes. And you may want to try to get the testimony of the next panel.

So just real quick, Dr. Haralson, it is ironic, because you pointed something out, it is very important, physicians are legitimately unhappy with the way CMS establishes reimbursement rates. We call it the Sustainable Growth Rate; it is unrealistic. So what they are proposing is what you basically were saying, and that is pay for performance. The amazing thing, we want you to use your independent judgment and choose that treatment and protocol, and of course, we are talking about medical devices, too, that will get you that result that we are seeking. Right? However, what we have in place today and what we are hearing, we are going to restrict your ability to pick that device, or even maybe the treatment that you in your professional opinion believe will result in the quickest recovery and such. Pay for performance. I know it is odd, and you go back and I am sure you have great discussions about who we are over here in Washington, and rightfully so.

Now, you heard the witness, Mr. Wilson, from CMS, and it appears his answers are really good. And he knows a lot more about this subject than all of us in here because that is his full-time job. But in your specific issue about exempting physicians for what you do, and it seems very reasonable, what was their response? Because surely they heard your objection and your request, and surely they responded. What was that?

Dr. HARALSON. Well, we did have some discussions with them. And frankly, at first they seemed to agree with us. And we thought actually they were going to exempt physicians from the competitive bidding, and especially from the—from the competitive bidding for the things that we supply, which are really just braces and splints. We don't do the other DME, the wheelchairs. We do like to have crutches so the patients can ambulate out of the office. But we assumed that they were going to exempt us. And we are frankly a little dismayed that we were not included, because they did exempt physical therapists and occupational therapists. And it is a little bit odd that, in many cases, orthopedic surgeons employ physical therapists, and so we have a situation where my employee can provide the DME, but I cannot.

Mr. GONZALEZ. And now, Mr. Staub, you heard Mr. Wilson, who indicated, sure, when we call the V.A.C. wound therapy, yours is not the only device out there. Now, people are going to say, you are not that objective, Charlie, KCI is in San Antonio. And there is an element of truth to that. But I also have been the beneficiary of a lot of information, and I know the studies that have taken place. I know the physicians and the clinicians. I know what they are saying out there about the superiority of a particular product or device. Not necessarily just yours.

Well, how do you respond? They have done their homework. They have done their research and FDA approval. It looks like you have all these other devices, and it doesn't matter if yours may be the device of choice by the physicians, the attending physicians.

Mr. STAUB. You know, Representative Gonzalez, it is very disappointing actually. That is our response. And the reason being is two points. Number one is that, you know, the way these products are approved, as he had said, there is a PMA or a 510(k). A 510(k) is a more basic approval which basically proves that the product is safe and says that it acts as though—acts the way you want it to act. Basically, it does what you say it will do. But clinical studies, really usage on a patient doesn't happen unless you have a PMA. So they come on to the market as predicate devices saying this is just like that one. But they are actually very, very different. Not only the way the products are made up and the way they act with the patient, but I think the second point that is most important is around this accrediting.

I mean, the accrediting that we saw was really just around financial capabilities of these companies, not around their ability to service or care for the patients by any means that these guys have mentioned I think a couple of times. You know, we have over 450 clinical nurses that are out in the field. We have over 1,200 service people that are out there that answer these calls late at night. And I don't think these companies that come in—and, you know, I use the term carpetbagger loosely—but you know, basically want to get

the bid to either sell the bid to someone else or to try to then find a supply and support that market. I think that is extremely disappointing for us, because we feel like we seriously help patients that are compromised and at home and have no one else to help them. And it is a less expensive alternative, quite frankly, than having their surgeons keep them in the hospital for another 2 weeks or 3 weeks until their wound heals.

So my response would be that it is disappointing that they haven't gone deep enough in understanding and accrediting potential suppliers.

Mr. GONZALEZ. Yeah.

And to Mr. Hite and Mr. Sutton and Mr. Einfalt, this committee is obviously the Small Business Committee, and we are very sensitive to what is going on out there, and our chief concern is really the impact of all of this on small businesses.

Dr. Einfalt, we are familiar with the average manufacturer's price, what it is going to do to you, because we have had other hearings. We have had our community independent pharmacists.

Mr. Hite, Mr. Sutton, we have had other hearings by different Subcommittees, and we are very familiar with some of the issues and the challenges in providing a service. I know we had a home care provider from Texas that was saying, just with the cost of gasoline, now we are talking about certain areas of Texas you drive forever, and that is not part of the calculation in arriving at what it takes for you to provide a service or a device. Now that is not realistic. That is not reality-based. So it is so important when you come and testify here.

My fear is that Mr. Hite and Mr. Sutton are probably going to be relegated at best to some sort of a subcontractor status. And that means a whole lot I think to small businesses today when you are the owner of a business and such and what will be dictated to you. So, again, I just want to say thank you for your testimony.

And I yield back, Mr. Chairman.

Chairman SHULER. Mr. Gonzalez, I want to thank you.

I want to really commend the hard work and dedication of your businesses, and their associations have been able to put forth the work in being here and for your testimony. I thank you so much.

And thanks for your testimony.

We are going to—very quickly, because we are going to call votes here, and it could be any minute now—to the third panel if we can. So if we can just quickly change out, thank you so much.

If we can get on the third panel, please. It is very important that we hear the third panel. We have got votes coming up very quickly.

Our next witness is Dr. Rebecca Wartman, owner of Doctors Vision Center in Asheville, North Carolina. She is testifying on behalf of the American Optometric Association.

Thank you for your commitment to being here. Thank you for your testimony. And I look forward to hearing it.

STATEMENT OF DR. REBECCA H. WARTMAN, OD, OWNER, DOCTORS VISION CENTER OF ASHEVILLE, ASHEVILLE, NORTH CAROLINA, ON BEHALF OF THE AMERICAN OPTOMETRIC ASSOCIATION

Dr. WARTMAN. Thank you. Mr. Chairman, and members of the committee, the American Optometric Association, representing over 34,000 doctors of optometry, would like to thank the committee for holding this important hearing.

My name is Dr. Rebecca Wartman, and I am the owner of Doctors Vision Center in Asheville, North Carolina. While I have been an optometrist for 21 years, I have been in Asheville for 11 of those years. As an optometrist and a small business owner, I am pleased to have the opportunity to provide testimony regarding the burdensome requirements established by the Medicare Modernization Act and the chilling effect on providing patient care.

Even though CMS has exempted physicians and treating practitioners from the competitive bidding program, under many circumstances, optometrists are still concerned with two requirements of the program which, if implemented, could have an adverse impact on Medicare patients.

First, we believe that requiring physicians and health care professionals to be accredited in order to continue supplying DME when treating patients is both financially and administratively burdensome.

Second, in the MMA, it appears that there is no recognition that health care professionals who supply and educate patients on the appropriate use of DME that is integral to patient care are very different from suppliers who furnish DME products to the public as a primary part of their business. Roughly 14,000 optometrists with DME supplier numbers prescribe lenses, frames and sometimes contact lenses to patients following cataract surgery. And these items are clearly an integral part of the practice of optometry. These benefits are typically provided only one time after cataract surgery.

Further, the 2004 CMS data indicates that health care providers supply slightly more than 3 percent of the total DME. It is unclear, therefore, what, if any, program improvement and cost savings would be realized by imposing these requirements on health professionals who only dispense DME when providing patient treatment. Since March 1st of this year, Medicare began requiring health care professionals to become accredited prior to obtaining a national supplier clearinghouse number. The accreditation process, as we have already heard, is time-consuming, expensive, and heavy on paperwork, costing up to $3,000 for a 3-year period.

Many optometrists, as well as other small business health professionals, do not want to or cannot afford this additional cost and regulatory burden. Apparently, only 4 of the 10 accrediting organizations will accredit optometrists.

As well, this accreditation can take months to complete. For optometry, it would essentially be impossible to recoup these costs given the amount of Medicare payments for the small number of DME products furnished to our patients. Therefore, it is difficult to understand why optometrists and other health care professionals—

it is not difficult to understand why optometrists and other health care professionals find it impractical to receive accreditation.

In fact, the American Optometric Association has already received numerous complaints from optometrists who have made the decision not to supply lenses, frames, and contact lenses after cataract surgery. If optometrists and other health care providers are faced with being unable to provide Medicare-covered DME products to their patients at the point of care due to these regulations, the only other alternative would be to refer the patient to a DME retailer supplier.

This delay in access to appropriate treatment or even worse could prevent the beneficiary from receiving the proper item because there is no DME retailer in close proximity. The costs of transportation, the need for more than one trip in many cases, and the burden of finding a provider will all be serious hurdles for many Medicare beneficiaries. These burdens are even greater for patients in nursing facilities and assisted-living situations, whom I personally serve many of those. As well, aphakic patients, those who did not have a lens implant after cataract surgery, are often fitted with contact lenses. And that presents a whole other array of health risks. And the contact lenses do fall under the DME.

In conclusion, the one-size-fits-all approach by CMS fails to recognize that DME suppliers comprise a very diverse set of individuals and organizations, including licensed health professionals and physicians, such as optometrists. The AOA believes that the accreditation and quality standards developed by CMS should recognize this diversity and be structured accordingly. And we believe that the MMA gives the agency sufficient flexibility to do so. We look forward to working with the Small Business—House Small Business 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 DME as a part of their care. Thank you.

[The prepared statement of Dr. Wartman may be found in the Appendix on page 131.]

Chairman SHULER. Thank you.

At this time I yield time to Mr. Braley to introduce our next witness.

Mr. BRALEY. Thank you, Mr. Chairman. I am pleased to have two of my constituents here today in the room, John Gallagher with VGM, and our next witness, Ms. Julie Weidemann, who is the director of Palmer Home Medical Supply in West Union, Iowa, which is a lovely county seat town of over 2,500 people.

And it is great to have you here.

Ms. Weidemann will share some of her 20 years of experience in the home medical equipment industry. And she will also be testifying on behalf of the VGM Group, which is the largest network of independent home medical equipment dealers in the United States, with more than 2,000 medical equipment provider members in more than 3,500 locations.

Welcome.

STATEMENT OF MS. JULIE WEIDEMANN, DIRECTOR OF PALMER HOME MEDICAL SUPPLY, WEST UNION, IOWA, ON BEHALF OF THE VGM GROUP

Ms. WEIDEMANN. Thank you.

Chairman Shuler and members of the Committee, I am Julie Weidemann, director of Palmer Home Medical in West Union, Iowa. I am pleased to come before this Subcommittee to discuss with you the profound risk of the DMEPOS competitive bidding program being implemented by the U.S. Department of Health and Human Services.

I have worked in the HME industry since 1988. I started my home care career as a respiratory therapist and, in 1994, created and instituted Palmer Home Medical Supply, a department of Palmer Lutheran Health Center, which is a 25-bed hospital in West Union. We have three locations. I employ 10 people. We serve 10 counties in rural northeast Iowa, covering 2,500 square miles. And close to 50 percent of my client base are Medicare clients.

I have the largest concern over the competitive bidding program due to the MMA 2003 provision that allows CMS to take the purported savings that is achieved in desperation bids from round one and apply pricing nationwide with the new fee schedule.

Earlier, Representative Braley asked the question how competitive bidding is going to affect rural providers. And what was stated was that it was only going to affect metropolitan areas, and really rural providers were exempt. That is not true. What CMS can do is they can take the data from these round one and two biddings, and they can impose an inherent reasonableness standard on the entire industry, which will mean that rural providers will have a 26 percent cut in reimbursement. So, no, I am not in a competitive bidding area, but I am still going to see the 26 percent cut that they are seeing in the metropolitan areas. If I have to take that 26 percent reduction, I will have no choice but to decrease the level of service I am currently providing. And with the price of fuel, I may need to decrease the territory I provide service to.

What then will happen to the patients out there in those outlying areas? What provider will be able to afford to help them? And if I am decreasing my territory, that means I most likely will need to cut staff.

My other major concern is competitive bidding will simply limit choice for beneficiaries and will dramatically reduce the service they have always received and need to receive. Can a company 3 hours away that gets the bid provide quality service compared to what I can provide when I am right down the street? My patients are going to suffer greatly from this program. Small business is going to suffer greatly as well and will not be able to survive a 26 percent cut.

And what happens to medical innovation? It will cease to exist in a low-bid environment. Better technologies are expensive. And with the huge national bureaucracy that is being created at CMS, an increase of approximately 1,600 employees, what kind of savings will really be achieved at the expense of patients and small business?

Also there has been a lot of talk this morning about discussion on quality standards and accreditation. To this date, the HME pro-

vider quality standards are still in draft form. There has been no final release yet. So we don't know exactly what our standards are going to be.

The new rent-to-purchase payment policy for home oxygen program enacted in the DRA requires that, after a 36-month rental period, title and responsibility for maintenance and service for all home oxygen stationary and portable technologies would be transferred to the Medicare beneficiary. Just last week, one of my respiratory therapists was in a Salvation Army store in Cedar Rapids, Iowa, and sitting there was an oxygen concentrator and three oxygen tanks for sale for 50 bucks; no doctor order required. Oxygen is a drug that must be prescribed by a physician. And when beneficiaries start owning this equipment, where will it go when they no longer need it? Obviously, a Salvation Army, maybe a local garage sale, on eBay, the Internet. As a respiratory therapist, this worries me to no end.

Oxygen, when used inappropriately and without proper training, has very dangerous consequences that could result in death from underdosing or overdosing, or deadly fire due to lack of training in the safe use and storage of the oxygen. Providers currently educate each patient and their caregivers on these very critical issues. The costs for providers is not in the equipment being provided. It is in the service. Patients don't call us for equipment. They call us for advice. We currently provide 24-hour emergency on-call service. We assist our patients with troubleshooting and proper use, equipment failures. We provide clinical assessments by respiratory therapists and nurses. Who is going to do all this when the patients own their own equipment?

I cannot provide these services for free, and not many of my fixed-income Medicare patients can afford to pay me extra out of their Social Security check for these services. So it will simply not get done, and patients will be hospitalized more often. In 2002, there were 673,000 hospitalizations for people with chronic lung disease. Their average length of stay was 5.2 days, making the average cost of that hospital stay $18,000.

In contrast, the current average annual cost for home oxygen therapy is $2,784, less than the average cost for one day in the hospital. I can provide this service for a whole year. Home care is the solution. It is not the problem with our medical industry and the Medicare expenditures that go out.

What does this mean to me, rural hometown HME providers, and all the providers in a competitive bid area throughout America? I live in an area of the country with a large elderly population. And with almost 50 percent of my clients on Medicare, I truly fear what will happen to my customers and my small business when the competitive bidding storm thunders its way into rural America. I cannot survive if I cannot serve Medicare beneficiaries, nor can I survive providing our current quality of product and level of service with a 26 percent cut in payment. Due to this competitive bidding storm, small business will be destroyed and beneficiaries will be left to fend for themselves, threatening their current access to care and their quality of life.

I call on Congress to immediately delay the implementation of this competitive bidding program. And as with any action that is

taken to avert the train wreck that is competitive bidding, I ask that Congress include a repeal of the imposition of the 36-month cap on oxygen. As a provider, I support the implementation of a rational alternative process to determine Medicare pricing for DME items and services.

I thank you for this opportunity. It has been quite an honor.

[The prepared statement of Ms. Weidemann may be found in the Appendix on page 137.]

Chairman SHULER. Thank you for your testimony.

Our final witness is Mr. Gary Gilberti, president and CEO of Chesapeake Rehab Equipment, from Baltimore, Maryland. He is testifying on behalf of the National Coalition For Assistive and Rehab Technology.

You will be recognized for 5 minutes.

STATEMENT OF MR. GARY GILBERTI, PRESIDENT AND CEO, CHESAPEAKE REHAB EQUIPMENT, BALTIMORE, MARYLAND, ON BEHALF OF THE NATIONAL COALITION FOR ASSISTIVE AND REHAB TECHNOLOGY

Mr. GILBERTI. Thank you, Mr. Chairman and members of the Committee.

On behalf of NCART and my company, Chesapeake Rehab Equipment, I appreciate the opportunity to be here today.

As Chesapeake Rehab, we participated in competitive bidding in two of the CBAs. And I can say I lived to tell about it, but I am not sure I am happy about it.

Just to understand a little bit about complex rehab technology, you have to understand a little bit about these businesses. Complex rehab technology companies, more than 50 percent of the providers in this sector are small businesses, with revenues of between $3 and $5 million annually. Most are privately owned, which are generally well entrenched in their communities and have established relationships with their customers and allied health professionals.

Complex rehab and assistive technologies are adaptive seating, positioning, and mobility devices that are evaluated, fitted, configured, adapted, and modified based on the unique clinical and functional needs of people with severe disabilities. These disabilities could include things as ALS, spina bifida, cerebral palsy, muscular dystrophy.

In fact, there is a young woman in the room today, Selen Dalton Cummings, who is a customer of mine. She is in a piece of complex rehab technology. And it helps her get to work every day and be a very productive individual in the community.

And just a little bit more what differentiates complex rehab technology companies from other home medical equipment providers is the level of products we supply and the level of staff required to provide them, and the amount of time and labor that is involved in that process. Companies that adhere to the long-standing service/delivery model that provides the best clinical outcome for consumers for complex rehab are required to employ certified staff and to run their operations in a certain way. All this comes with a very high cost.

In a study performed by a D.C.-based economics firm for NCART, companies operating in this field experienced a net operating income of 1.6 percent. That is a very thin line. This is based on nonproduct costs in the 50.5 percent range and product costs of 47.9 percent for these companies. With such high nonproduct expenses and such minimal net operating income, complex rehab technology companies are already unstable. Coupled with cash flow challenges in dealing with third-party payers and then add the increase of things like fuel and payroll costs increasing the way they are, these companies are even more challenged to remain viable.

It is important to note that suppliers and manufacturers of complex rehab technologies have already absorbed significant cuts in reimbursement resulting from coding changes and congressionally mandated reimbursement cuts. Moreover, the CPI increase for Medicare fee schedule for existing HCPCS codes has been frozen for almost a decade, while costs associated with the provision of this technology have increased. The DME industry generally has only received one permanent Medicare fee schedule increase since 1998.

Round one of competitive bidding continues to move forward in spite of many inequities and controversies. The areas of concern range from both the resulting prices and their calculations to the actual winning bidders and how they were selected. CMS continues to claim that it has addressed many of the concerns appropriately, but the fact still remains that many small businesses have already been injured by this program.

When you look at competitive bidding in the complex rehab area, CMS has claimed to realize a 15 percent savings in that area. If you use the math that I have given you already, as far as where rehab companies are, with a 1.6 net operating margin, you take 15 percent out of what tends to be about 30 percent of their business, they are below water.

There is also the issue that there are companies that are doing business in competitive bidding areas who are not historically operating in those areas. In Pittsburgh, for example, where I was not able to win a bid, two of the four companies that were offered the bid either have not operated in that business—or in that CBA or in that business as far as complex rehab.

Additionally, CMS claims there are accreditation standards in place. One of the winning bidders in many of the CBAs was able to get in under a loophole that they were accredited under standards that were not in place by the time the competitive bidding was put in place. For instance, now in order to be a complex rehab provider, you have to have certain certified individuals; you have to operate a certain way; and the accrediting bodies have rehab standards. Those weren't in place. And these companies were able to get through based on a loophole.

In conclusion, I just would hope that Congress would embrace H.R. 2231, which would allow for the exemption of complex rehab technology from competitive bidding and would allow that Medicare beneficiaries with disabilities would be protected from this problem.

Thank you.

[The prepared statement of Mr. Gilberti may be found in the Appendix on page 146.]

Chairman SHULER. Thank you for your testimony.

Obviously, they have called votes. What we are going to do is, each of the members will ask one question. And hopefully, we can give everybody the opportunity to kind of expand more on their testimony.

I first would like to ask Dr. Wartman, if there is no change in the current regulations, what effect will the accreditation requirements have on patient care and access to DME?

Dr. WARTMAN. Well, as I said, some optometrists have already decided to drop out of DME suppliers because they needed to recredential with the national clearinghouse and been told that they couldn't if they were accredited.

So if I am not a supplier of glasses after cataract surgery, those patients that I have had a really long-standing relationship with, been my patient for a number of years, I helped them through the process of deciding to have cataract surgery, care after cataract surgery; I will have to look at them and say, now you have to go somewhere else to find your glasses. It is one time after cataract surgery.

If I have a patient that doesn't have a lens implant, that is aphakic, and has the really thick Coke bottle glasses or contact lenses and glasses, then I have to look at them and say, I can't supply your contacts. In many cases, I can't even fit those, because fitting it is really an integral part of supplying it. I can't actually fit it unless I have it. And then I can't make adjustments to it.

So while those patients are becoming fewer, there are still a lot of those patients out there. So it will really have a big impact on the patients.

Financially, I don't make a lot of income off of the durable medical equipment because it is not very much for us. But to have to jump through those hoops and pay a huge credentialing fee and all the burden of trying to figure out how to get through that process, as well as be credentialed by the national clearinghouse supplier in addition to all my State licensure requirements, I think a lot of us would choose just not to provide those.

But that's not fair to the patients.

Chairman SHULER. Thank you.

I will now yield to Mr. Gonzalez.

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

Just quickly, Dr. Wartman, I think we are hearing you. I think you are aligned with Dr. Haralson, saying, look, if we are the physicians, the professionals, there has to be an exception. This is common sense, by the way. And I think we get that. And let's see what we can do about it. I don't think it is going to impact in any measurable amount CMS's efforts in reducing costs.

Ms. Weidemann, Mr. Gilberti, I am trying to rush this because we are going to have to go and vote, and I don't want to keep you here, and I know that Bruce might have something he wants to ask.

Some people will say, and CMS may say, who cares if you guys are relegated to subcontractor status? You still have a business.

You are still a small business. The way I see it, and I want you to tell me, is the problem is that the big contractor that got the bid, that had the best bid, can be as unrealistic as they want to be because they are just going to be passing it onto the subcontractor. They are going to find somebody out there, hopefully, or it is not going to be really viable or it is going to work. What is the big disadvantage of you just being part of subcontracting system with the winning bid?

Mr. GILBERTI. Congressman Gonzalez, I have won in one CBA and I didn't win in another CBA, so I have seen both sides of this.

Mr. GONZALEZ. Yes, sir.

Mr. GILBERTI. And as winner, I don't feel like a winner because of the pricing, because a lot of people bid out of fear and intimidation to just try and maintain their customer base.

But as a subcontractor, I am going to have to give up another portion of margin in order to participate. That means, as subcontractor, one of the existing winners is going to want a percentage out of me. So the price then goes down probably another 10 percent on me. And I can't operate on that. But in order to serve my clients, I am going to have to accept some of that.

Mr. GONZALEZ. I thank you very much for your testimony.

I yield back, Mr. Chairman.

Chairman SHULER. Mr. Braley.

Mr. BRALEY. Thank you.

Ms. Weidemann, I want to follow up on the point I made in the first panel about my perception that the entire purpose of this competitive bidding process is to adopt a bigger-is-better mentality. And you were here when the CMS representative testified that that was not his perception of the bidding process. But in your written statement, you included some interesting figures that came out of the round one bidding process, and I think it is very relevant to the discussion we are having today.

You wrote only 5 percent of the eligible small business providers were offered a contract and about 16 percent of the large providers. And that is from an earlier perception that 85 percent of the businesses engaged in this industry were small businesses. So one of the things that I am troubled by as a person who represents a heavily rural district is if this was truly a free-market environment, then the large companies would have the same incentive to compete in rural America as they would in urban America. But if that were true, then we would see Comcast providing cable TV services in West Union, Iowa, and we know that is not true. So from your perspective as a small business owner living in a small community, would you care to respond to the CMS representative about your perception of what is going on here?

Ms. WEIDEMANN. Well, we already basically see it in the VA system. Patients on VA that are on oxygen in my town of West Union, the contracts that the VA has at Iowa City, they come to that patient's home every month, they bring them six oxygen tanks. And if they run out, it is their problem. They can go back to Iowa City themselves to get more tanks or they just go without. And that is what is going to happen if—if the big company gets the bid, the little guy down the street for—I think right now I have a patient last week that called me on a Sunday morning. I forgot to call you and

tell you I was out of tanks on Wednesday, and I really would really like to go to church this morning. I met them at the office and gave them their tank. That is not going to be a viable option anymore when these big companies get the bid and they are too far away.

Mr. BRALEY. So, in some cases, it could be a life-and-death matter?

Ms. WEIDEMANN. Definitely. They are going to go without.

Mr. BRALEY. I yield back, Mr. Chairman.

Chairman SHULER. I would like to thank the gentlemen for their questions. I thank all of you for your time, your commitment, and for all of the witnesses here today.

I thank Mr. Fortenberry for his continued support in a bipartisan way so that we can get to this. And I also want to thank CMS, the staff that has remained here to hear this testimony. I think it is so important that we all understand how we can work with our colleagues. But not only with this committee, with some of our other committees who have jurisdiction as well. So I look very forward to working with all of you. And, again, thank you for your testimony.

I ask unanimous consent that the record be open for 5 days for members to submit their statements. Hearing no objection, so ordered. This hearing is adjourned.

[Whereupon, at 1:08 p.m., the subcommittee was adjourned.]

Congress of the United States
U.S. House of Representatives
Committee on Small Business
Subcommittee on Rural and Urban Entrepreneurship
2361 Rayburn House Office Building
Washington, DC 20515-6315

STATEMENT
of the
Honorable Heath Shuler, Chair
Subcommittee on Rural & Urban Entrepreneurship of the
House Committee on Small Business
Hearing on the
"Competitive Bidding for Durable Medical Equipment: Bad Medicine for Small Suppliers"
Wednesday, May 22, 2008

Access to health care is becoming increasingly critical for our seniors. By 2015, the Baby Boom population in this country will reach 77 million. So it's crucial to consider how we will care for these older adults -- and how we will pay for that care.

In 2007, health care costs in the United States reached $2.3 trillion. Without a doubt, it is one of the greatest challenges in America and if we are not careful, it will bankrupt this nation. The question before us today is whether addressing America's Medicare challenge requires hurting the very small health care providers who have committed themselves to serving our Seniors.

This hearing will examine the implementation of the Competitive Bidding Process for Durable Medical Equipment. While this program was created as a way to curb Medicare spending, this subcommittee will review if CMS is properly considering the impacts on small health care providers. CMS maintains that competitive bidding will not only ensure access to care, but reduce out-of-pocket expenses for seniors, and improve the effectiveness of payment.

However, it is not clear that the new program will meet this goal without driving small health care providers out of business and limiting access to care. The results for the first demonstration project were mixed, at best. CMS's competitive bidding program for durable medical equipment was implemented in 10 cities last year.

The bidding process created a number of problems for DME small business providers. CMS incorrectly disqualified some companies from participating due to clerical problems. In a number of situations, contracts were awarded when the bidder had no local presence and no history of providing a given product or service. This clearly does not meet the goal of ensuring access to care for beneficiaries.

Since Asheville, North Carolina is in the second round of competitive bidding, I have been hearing first-hand about these problems. Small firms are an essential part of this health care market, as well as across the nation. They fill many of the gaps larger businesses either cannot or will not fill.

Like a number of my colleagues, I worry that CMS has not considered the unintended consequences that may result from the program. This includes the possibility that Medicare beneficiaries may lose the right to choose the trusted care and service of their local provider.

Limiting suppliers could have a devastating impact on rural communities. Suppliers could have to severely limit outreach to rural areas. At a time when these communities are already facing health care shortages, CMS should not be making the problem worse.

Also, I believe that rural communities would be unfairly impacted by competitive bidding because of the nature of the program. Health care practices could be forced to close their doors, and working families would lose their jobs.

Unfortunately, CMS has not taken any corrective actions to fix the competitive bidding process and the impact it will have on small suppliers. I think everyone in this room agrees that the federal budget simply cannot sustain the current growth rate in Medicare spending. However, we must also ask if there are better means to achieve this end.

U.S. House of Representatives
SMALL BUSINESS COMMITTEE
Subcommittee on Rural and Urban Entrepreneurship

Wednesday, May 21, 2008

Opening Statement of Ranking Member Jeff Fortenberry

Competitive Bidding for Durable Medical Equipment: Bad Medicine for Small Suppliers

Good morning. Thank you, Mr. Chairman, for holding this hearing on "Competitive Bidding for Durable Medical Equipment: Bad Medicine for Small Suppliers."

The House Small Business Committee, this subcommittee, and our nation recognize that small business is critical to the country's overall economic well-being. The competitive pressures, creativity, and innovation that small businesses bring to the marketplace are the hallmarks of entrepreneurship and the keys to job creation and economic growth.

In many areas of our economy, the needs of rural America are uniquely different than those of urban areas. Few issues are more important to rural Nebraskans than access to quality health care services and providers. Small businesses depend on access to quality health care as a key component of efforts to attract and retain a vibrant workforce. Small employers also play an important role in the delivery of health care services and products in many rural markets. For example, 103 of the 142 pharmacies in my district are small, independently run employers.

As we all know, Congress in 2003 mandated that the Centers for Medicare & Medicaid Services (CMS) implement the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive bidding program. It is, therefore, appropriate that Congress provide oversight as the program moves forward.

This competitive bidding program was established to reduce beneficiary out-of-pocket expenses and save taxpayer dollars while ensuring beneficiary access to quality items and service. The Centers for Medicare and Medicaid Services (CMS) is scheduled to implement the competitive bidding program in phases. Round one encompasses 10 competitive areas and is on-going; Round 2 encompasses 70 competitive areas to be implemented in 2009 and additional areas are scheduled to follow after 2009. As part of the bidding program, CMS is required to take appropriate steps to ensure that small suppliers have an opportunity to be considered for participation.

Congress, through its oversight role, must ensure that this process is implemented in a way that does not impede the competitiveness of our small pharmacies and suppliers, particularly in rural areas. Many small firms remain competitive by delivering high quality care to their patients. As CMS goes forward with this program, it is important to ensure that smaller suppliers, who particularly emphasize quality service, are left in a competitive position.

We have excellent witnesses here today to provide us with insight into what issues need to be addressed to improve this program. Thank you Mr. Chairman, and I yield back the balance of my time.

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NYDIA M. VELÁZQUEZ, New York
Chairwoman

STEVE CHABOT, Ohio
Ranking Member

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515-6315

Opening Statement
Chairwoman Nydia Velázquez

Congress Shuler has been an advocate for small business on a number of fronts. Whether it's he's addressing energy costs, health costs, or any other small business concern, he has made small business his priority. Thank you Congressman Shuler, for holding today's hearing and bringing this important issue forward.

Congress must not forget that most durable medical equipment suppliers are not only important small businesses; they are a vital part of this nation's health care safety net. Everyday the elderly depend on DME suppliers for medical guidance and support. And they are often the only medical assistance some patients see in their community.

Once again, I find myself before CMS and the health care community asking the question -- What is going on? Over the past month alone, the Small Business Committee has held three hearing involving the Centers for Medicare and Medicaid Services. I don't think I would be alone in saying – there is a problem. This is not the first hearing we have held on the question of Competitive Bidding.

My concern is that CMS has little regard for how its decisions are impacting small businesses providing care to America's elderly. I have heard from numerous health care organizations asking this Committee to help them be heard. CMS like any agency must be accountable. And today's hearing is as much about accountability as it is about the challenges of the DME program.

Again, thank you Congressman Shuler for holding this hearing. And I yield back the balance of my time.

May 21, 2008

Congressman Bruce Braley
Opening Statement

Hearing on "Competitive Bidding for Durable Medical Equipment"

Thank you Chairman Shuler, and thank you for holding this hearing.

I would like to thank Ms. Julie Weidemann, a constituent from my district and Director of Palmer Home Medical Supply, for taking the time to come to Washington, DC to testify before the Small Business Subcommittee on Rural and Urban Entrepreneurship on this important issue.

In 2003 Congress passed the Medicare Modernization Act (MMA), which required the Centers for Medicare and Medicaid Services (CMS) to launch the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Bidding Program. While on the surface this may seem like a good idea, there is evidence that it could have a devastating impact on DMEPOS industries.

Companies currently receive a government-set fee to distribute durable medical equipment for patients' home use. Under the competitive bidding system, however, companies would have to submit a bid indicating how low of price they would be willing to accept. Medicare would then limit distribution rights in a particular geographic area to the lowest bidders. In 2007 the DMEPOS Competitive Bidding Program started in the 10 largest metropolitan statistical areas (MSAs) and in 2009 it is scheduled to be expanded to the largest 80 MSAs.

I have many concerns about this competitive bidding process. This year I joined many of my Colleagues in sending a letter to the Centers for Medicare and Medicaid Services. In this letter, we expressed concerns with the level of small business participation in the competitive bidding program. Even the small businesses who are awarded contracts will be challenged to conduct business at reduced reimbursement rates because they cannot compete with large companies that have economies of scale.

Also, there are many bidders that have been rejected by CMS on claims they had not submitted sufficient financial information or that they had made other minor errors on their applications. Although these rejected bidders have made claims that they have evidence to the contrary, they have no appeal rights.

Furthermore, the program requires supplier accreditation for those participating in this program. This can create significant administrative and financial burdens on small suppliers and pharmacies. Many of these suppliers and pharmacies are already required to have a number of accreditations for providing care.

The biggest concern I have, however, regarding CMS's proposal is that it could put small providers, like Palmer Home Medical Supply, out of business. Palmer Home Medical Supply currently serves ten counties in rural Northeast Iowa and almost half of their business includes Medicare beneficiaries. The potential loss of suppliers could threaten these rural areas, which are more likely to have elderly populations. It is essential that our communities continue to have access to high-quality and great service from these small business providers.

I understand that the intent of the DME competitive bidding program is to provide cost savings for the Medicare program and its beneficiaries, and I appreciate these efforts. But we need to ensure that beneficiary access, quality of care, and small businesses are not harmed by this program.

The CMS competitive bidding for durable medical equipment project leaves too many questions unanswered. We need to take a step back to think about the true impact this project would have on small providers and ultimately on the communities where they reside. It is important to explore whether there is a rational alternative for determining Medicare pricing for DME items and services. There are too many indications that the current bidding system is flawed.

I look forward to hearing from our witnesses today and am hopeful that we can come up with a solution for Medicare reimbursement that does not pose so many potential risks for providers and patients.

Thank you Mr. Chairman, and thank you to the witnesses for coming in today.

Statement of Rep. Jason Altmire
Committee on Small Business Hearing
"Competitive Bidding for Durable Medical Equipment"
May 21, 2008

Thank you, Chairman Shuler, for holding today's hearing to discuss the Centers for Medicare and Medicaid's (CMS) competitive bidding program for durable medical equipment. Last October, I held a hearing as Chairman of the House Committee on Small Business Subcommittee on Investigations and Oversight on how CMS' competitive bidding program was going to impact small home medical suppliers. Unfortunately, the concerns raised by the witnesses last fall been proven to come true. The roll out of Round One has placed tremendous burdens on small medical suppliers and will undoubtedly negatively affect the quality of care that patients will receive.

I am concerned that CMS' management of the DMEPOS competitive bidding program is going to force many small home medical suppliers out of business. Small suppliers make up 85 percent of the home medical equipment industry. As a result of the competitive bidding program, it is likely that many of the home medical suppliers that did not win a bid will be forced to close their doors for good as a result of no longer being able to participate in Medicare. Patients who have come to rely on their relationship with local, small supplier are not going to receive the same quality of care that they have become accustomed to.

I continue to have concerns about the way CMS is implementing this program, and along with a number of my colleagues, have called for a delay of implementation of Round One so that issues of concern can be addressed before we proceed to Round Two. It is my hope that CMS will work with Congress to resolve the problems expressed by today's witnesses and the home medical supplier community.

Chairman Shuler, thank you again for holding this important hearing today. I yield back the balance of my time.

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Testimony of
Laurence D. Wilson
Director, Chronic Care Policy Group,
Center for Medicare Management
Centers for Medicare & Medicaid Services

Before the
House Committee on Small Business
Subcommittee on Rural and Urban Entrepreneurship
On
DMEPOS Competitive Bidding Program

May 21, 2008

Good morning Chairman Shuler, Ranking Member Fortenberry, 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 supplier fraud, ensure beneficiary access to high quality DMEPOS items and services, and save taxpayers billions of dollars.

Overview

CMS is the largest purchaser of health care in the United States, serving over 92 million Medicare, Medicaid, and SCHIP beneficiaries. Medicare alone covers roughly 44 million individuals, with total gross Medicare benefit outlays and administrative costs projected to reach approximately $499 billion in Fiscal Year (FY) 2009.[1] CMS projects that gross spending for Medicare will equal approximately $8.7 billion on DME alone in 2009. Each year, DMEPOS suppliers provide items and services including power wheelchairs, oxygen equipment, walkers and hospital beds to millions of Medicare beneficiaries.

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

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

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

Table 1: Illustrative Comparison Prices Pre-Competitive Bidding

DMEPOS Device (rank by use)	*CMS Fee (% above average internet price)*	*Illustrative Average Internet Pricing*	*CMS payment above average internet 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 for certain equipment and supplies will be calculated based on competitive bids submitted by accredited suppliers that meet both quality and financial standards. Suppliers who meet all of the requirements of the program and submit bids in the winning range will be awarded contracts in designated competitive bidding areas. These Medicare contract suppliers will then serve beneficiaries in the 10 competitive bid areas and will be monitored by CMS on their performance, quality and customer service. Requiring suppliers to submit bids, including information on price, accreditation, and financial standards will ensure continued access to high-quality medical equipment and supplies at more reasonable prices to beneficiaries and the Medicare program. These changes, which

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 reflected in the amount of money that beneficiaries will save as a result of lower coinsurance across the board for these products. Competitive bidding will successfully reduce the amount Medicare will pay for these items 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 participating in the initial phase of competitive bidding and in each product category, beneficiaries will see an average savings of 26 percent when the new payment rates go into effect on 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 will be reduced to $140.82 per month. The beneficiary, who has been paying coinsurance of $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 some commonly used items, for which Medicare pays 80 percent and beneficiaries pay 20 percent of the allowed amount following payment of the

[2] Federal Register, April 10, 2007, page 18079
[3] CMM data derived from bid results

annual Part B deductible, is summarized in the following chart[4]:

Examples of Medicare and Beneficiary Savings

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
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 stores (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 in the mail, they can elect to obtain them from a local store with no reduction in the allowed payment amount or beneficiary coinsurance amount.

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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

Quality and Financial Standards

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

Quality and Accreditation Standards. The MMA required the establishment of quality standards for DMEPOS suppliers to be applied by independent accreditation organizations. The quality standards address the set up and delivery of items and services, beneficiary education on the use of these products, suppliers' accountability, business integrity, performance management, and other areas. CMS conducted a wide variety of activities to involve stakeholders (including many targeted specifically for small business suppliers) and the public in development of these standards. Specifically:

- We conducted focus groups early in this process to provide small suppliers with an opportunity to share concerns about the impact quality standards would have on their businesses.
- We consulted with various stakeholders, including small supplier business owners, physicians, homecare association members, trade association members, accreditation organizations, clinical experts, and industry attorneys.
- We presented draft quality standards to the Program Advisory and Oversight Committee (PAOC) to provide advice on the Medicare DMEPOS competitive bidding program and quality standards.
- On September 26, 2005, we posted the draft standards on our web site for a 60-day public comment period that ended November 28, 2005.
- We held a special Open Door Forum to explain the draft quality standards and to solicit comments.

CMS received more than 5,600 public comments on the draft quality standards. Based on these comments, we made significant revisions to reduce the burden on small suppliers while continuing to ensure quality services for Medicare beneficiaries. All suppliers selected as Medicare contract suppliers in Round I of the competitive bidding program

must be accredited under these standards, and all DMEPOS suppliers nationally must be accredited by September 30, 2009.

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

It is important to note that the financial documentation requirements were crafted in a way that considers small suppliers' business practices and constraints, while remaining consistent with the financial standards mandate of the MMA. We have limited the number of financial documents that a supplier must submit so that the requirement will be less burdensome for all suppliers, including small suppliers. We believe we have balanced the needs of small suppliers with the needs of beneficiaries in requesting documents that will provide us with sufficient information to determine the financial soundness of a supplier, regardless of its size.

Final Regulations

Two of the goals of CMS' final regulations implementing the competitive bidding program were ensuring that beneficiaries maintained access to quality items and services, and that small suppliers had an opportunity to participate in the program.

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

- Contract suppliers must be accredited and meet the newly established financial and quality standards, and DMEPOS quality standards and accreditation requirements and, as a result, will maintain a business model that that supports quality, customer service, and access to care for beneficiaries. The independent accrediting organizations will play a key role in ensuring that contract suppliers continue to meet these quality standards.

- CMS' regulations require that multiple contract suppliers are selected to meet beneficiary demand in each competitive bidding area. This means that beneficiaries will have access to the services they need and that competition among winning suppliers, based on quality, customer service, will provide beneficiaries with choices regarding the source of their medical equipment and supplies.

- For the first time in the history of the Medicare program, the performance of suppliers will be monitored through beneficiary satisfaction surveys that measure their level of satisfaction with the services they receive from contract suppliers.

- Beneficiaries will have no financial liability to a non-contract supplier unless they are presented with and sign an advance beneficiary notice before a product is furnished to them. This protects beneficiaries from inadvertent financial liability in excess of what a contract supplier could offer

- When a physician specifically prescribes a particular brand name product or mode of delivery to avoid an adverse medical outcome, contract suppliers are required either to furnish that item or mode of delivery, to assist the beneficiary in finding another contract supplier in the competitive bidding area that can provide that item or service,

or to consult with the physician to find a suitable alternative product or mode of delivery for the beneficiary.

- Beneficiaries will be able to obtain repairs of equipment they own from either a contract or non-contract supplier with a valid Medicare billing number.

- Replacement parts needed to repair beneficiary-owned equipment may also be obtained by a beneficiary from either a contract or non-contract supplier with a valid Medicare billing number, even if the parts are competitively bid items.

- Contract suppliers are required to make available the same items to beneficiaries that they make available to non-Medicare customers. For transparency, we will post on our web site a list of brands furnished by each contract supplier.

- Under the grandfathering rules, a beneficiary will have the opportunity to make arrangements with a non-contract supplier that will allow the beneficiary to continue to receive certain rented items from the same supplier (grandfathered supplier) that had been furnishing the item to the beneficiary before the implementation of the competitive bidding program, provided the supplier is willing to do so. If a non-contract supplier agrees to furnish "grandfathered" items to one beneficiary, it must furnish those items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier.

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

The first round of the DMEPOS competitive bidding program is now complete. During the implementation of this program, CMS adopted numerous strategies to ensure small suppliers have the opportunity to be considered for participation in the program. For example:

- CMS worked in close collaboration with the Small Business Administration to develop a new, more appropriate definition of "small supplier" for this program. Under this definition, a small supplier is a supplier that generates gross revenues of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue rather than the previous standard of $5 million. We believe that this $3.5 million standard is representative of small suppliers that provide DMEPOS to Medicare beneficiaries.

- Further, recognizing that it may be difficult for small suppliers to furnish all the product categories under the program, suppliers are not required to submit bids for all product categories. The final regulation implementing the program allows small suppliers to join together in "networks" in order to meet the requirement to serve the entire competitive bidding area.

- In addition, to help ensure that there are multiple suppliers for all items in each competitive bidding area (CBA), each bidder's estimated capacity, for purposes of bid evaluation only, was limited to 20 percent of the expected beneficiary demand for a product category in a CBA. This policy ensures that multiple contract suppliers for each product category were selected and that more than enough contract suppliers are selected to meet demand for items and services in area. For most areas and product categories, the result of this policy will be an increase of the number of contracts awarded by CMS beyond the statutory threshold of two contracts per product category per CBA.

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

CMS recognizes that under existing Medicare law and policies, physicians and other treating professionals sometimes supply certain items of DMEPOS to their patients as part of their professional service. The competitive bidding program preserves this physician-patient relationship by allowing physicians and other treating practitioners to continue supplying certain items to their patients without participating in the bidding process.

Considerations for Low Population Density Areas and Rural Areas:
The statute also provides CMS with discretionary authority for exempting low population density areas within urban areas and rural areas that "are not competitive" from competitive bidding unless there is a significant national market through mail order for a particulate item or service. In the final rule, we indicated that we were finalizing our proposal to allow for the use of this authority if data indicated that an area was not competitive based on one or more of the following indicators:

- Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;
- Low number of suppliers of DMEPOS relative to other similar geographic areas; and
- Low number of Medicare beneficiaries receiving fee-for-service benefits in the area relative to other similar geographic areas.

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

exempted during Round Two.

The Bidding Process

The initial round of DMEPOS competitive bidding (Round 1) officially closed on September 25, 2007. We received a total of 6,209 bids for the competitively bid products across all 10 Metropolitan Statistical Areas (MSAs) in which CMS is proceeding with competitive bidding. 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 during the initial round of contract offers. Winning bids were offered a contract and as of April 18, 2008, 1,254 contracts have been signed by suppliers, a 96 percent acceptance rate. We are aware that a number of suppliers had their bids disqualified, and the majority of these were for failing to submit the supporting financial documentation that was outlined in the Request for Bids. This documentation is critical for determining whether suppliers meet financial standards, as required by the MMA. These standards are essential to ensure that Medicare contracts only with financially sound suppliers capable of serving beneficiaries needs over the life of the contract.

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 1,000 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.

[5] www.dmecompetitivebid.com

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 Center 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 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 should be receiving an email notice that information about the program requirements is available.

Our outreach strategy is administered both at the national and the regional level. Our CMS Regional Office staff has 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 will 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 may 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 the 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 the 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.

Conclusion

The first round of the competitive bidding process has proven to be successful. Medicare beneficiaries in CBAs will realize, on average, a 26 percent savings on certain commonly used DMEPOS, and small suppliers account for 64 percent of the winning bids. CMS has taken care to implement this program in a way that emphasizes the needs of beneficiaries while addressing the concerns of small suppliers. CMS has already begun a comprehensive outreach and education campaign in order to ensure a smooth transition for beneficiaries come July 1. We set out to provide beneficiaries with quality DMEPOS, at a lower price, from reliable suppliers in communities. We have lower prices, we have reliable suppliers and we are in the process of educating beneficiaries and suppliers about this new program. Our extensive monitoring network will signal any issues that arise and allow us to move to correct them quickly and efficiently.

TESTIMONY OF ROBERT H. HARALSON, M.D., M.B.A.

ON BEHALF OF

THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

ON

Competitive Bidding for Durable Medical Equipment: Bad Medicine for Small Suppliers

BEFORE THE HOUSE SMALL BUSINESS COMMITTEE

SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP

May 21, 2008

Testimony of
Robert H. Haralson, M.D., M.B.A.
On Behalf of
The American Association of Orthopaedic Surgeons
On
Competitive Bidding for Durable Medical Equipment: Bad Medicine for Small Suppliers

Before the Subcommittee on Rural and Urban Entrepreneurship
May 21, 2008

Good afternoon Mr. Chairman, Mr. Fortenberry, and members of the Subcommittee. I am Dr. Bob Haralson, and I serve as the executive director of medical affairs for the American Association of Orthopaedic Surgeons and am here on behalf of the AAOS which represents more than 17,000 board-certified orthopaedic surgeons.

I would like to thank you for the opportunity to present our concerns with the many changes being implemented by law and regulation concerning durable medical equipment, prosthetics, orthotics and supplies- collectively referred to as DMEPOS. We share Congress' aims of increasing the quality of patient care, eliminating fraud and abuse in federal health care programs, and reducing the costs of delivering care to beneficiaries, and it is our pleasure to appear before you today to continue our work toward those goals.

With that said, I would like to highlight, what we believe to be the unintended consequences of applying rules meant for retail DMEPOS suppliers to physicians in small practices across the country who provide certain DMEPOS as part of providing

high quality care to their patients. It is important to note that we are talking about physicians who supply DMEPOS *only to their patients*, not to the general public. And because many of our physicians who provide DMEPOS to their patients are essentially small businesses and many provide those items to their patients because they are the only "supplier" in rural areas, we are especially appreciative of your willingness to discuss this issue today.

* * *

In the field of orthopaedic surgery, we have several sub-specialties that are especially reliant on the provision of DMEPOS to meet basic patient care needs such as foot and ankle surgeons and sports medicine. As you well know, the provision of DMEPOS is not the main facet of the care we provide to patients, but it is a critical part of ensuring that many patients are able to ambulate out of our offices as safely as possible.

When analyzing the impact of the new rules and regulations around DMEPOS, including competitive bidding, it's important to remember that, from the physician perspective, there are different rules that apply to the different categories of DMEPOS.

(1) Durable Medical Equipment- As you are probably aware, physicians are not allowed to supply most DME to patients because of the Stark self-referral regulations. However, because some DME is so important to a patient's ability to safely leave the physician's office- and so important for preventing

further injury an exception from the Stark prohibition was created for several items. In the area of orthopaedic surgery, this exception includes crutches, canes, walkers, and folding manual wheelchairs. Physicians are able to provide these items to their patients if the arrangement fits within the Stark in-office ancillary exception.

(2) Orthotics- The provision of orthotics to patients in the course of care is also incredibly important. According to the U.S. Code, the definition of orthotics includes "leg, arm, back, and neck braces and artificial legs, arms, and eyes." Orthotics are treated differently under regulation than DME in that there is not an outright prohibition on physician provision of orthotics. In order to provide patients with orthotics and submit a claim to Medicare, physicians are required to ensure that they fit the arrangement into the Stark in-office ancillary exception.

(3) Prosthetics- The final major category is prosthetics, defined in the U.S. Code as items that "replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care)." While the provision of items meeting this definition is important to other specialties, the current rules have not substantially impacted the care that orthopaedic surgeons provide to their patients. In addition, Congress did not authorize CMS to include prosthetics as part of the competitive bidding program.

With that groundwork laid, I'd like to take you through some of the concerns that we have regarding new and revised rules pertaining to the provision of DMEPOS to our patients. While I know that our focus here today is the competitive bidding program, I'd like to give you the full picture of how the provision of DMEPOS to our patients is becoming increasingly difficult- including the potential impact of the competitive bidding program. Specifically, I'd like to address:

(1) The Application of DMEPOS *Quality Standards* to Physician-Suppliers;

(2) The Quality Standard *Accreditation* Process for Physician-Suppliers;

(3) The Impact of the DMEPOS *Competitive Bidding* Program on Physician-Suppliers

Collectively, these changes threaten to interfere with the continuity of patient care and the primacy of the patient-physician relationship and significantly increase the administrative burden of many physicians participating in the Medicare program.

DMEPOS QUALITY STANDARDS & PHYSICIAN-SUPPLIERS

In order for a physician to be able to provide allowed DMEPOS to their patients and bill Medicare for those products, the physician must not only be enrolled to participate in Medicare as a physician- but must also enroll as a DMEPOS "supplier." The rules make no differentiation between large retail DMEPOS suppliers and physicians who are also serving as DMEPOS suppliers solely during the course of caring for their patient.

As directed by Congress, CMS has been going through the process of issuing new "Quality Standards" for suppliers of DMEPOS. I'd like to personally thank CMS staff for their willingness to work with us on how these Quality Standards are applied to physicians who enroll as DMEPOS suppliers. These are Quality Standards that must be met in order to submit DMEPOS claims to Medicare; and these same Quality Standards must be met in order to submit a bid under the competitive bidding program.

Our major concerns regarding the Quality Standards are two-fold:

First, we are concerned about the roll-out and opportunity for input regarding these DMEPOS Quality Standards. The impact of these standards is wide-reaching - and because of that is something that requires broad input. As I mentioned, we have been appreciative of CMS' willingness to work with us on the standards. But with something as important as the quality of the care and access to the supplies that our patients need, we believe the Quality Standards should have been published through the formal rulemaking process. Such a process would have ensured that all stakeholders were aware of the potential impact of these standards, and it would have ensured that CMS shared the analysis behind what was included, what was excluded, and why they applied the same standard to physicians that they applied to other suppliers.

Second, the AAOS believes that a "one-size fits all" approach to the Quality Standards is not in the best interest of patients and will have an adverse impact on the patient's ability

to access DMEPOS from their physician. We have made CMS aware of these concerns, and while staff have acknowledged the difficulties of applying Quality Standards to physician-suppliers, the AAOS is concerned that CMS believes it lacks the authority from Congress to provide flexibility for physician-suppliers in setting the Quality Standards. This is certainly an area where we request the Committee's assistance.

THE QUALITY STANDARD ACCREDITATION PROCESS

The second major topic I'd like to bring to your attention is the burden of the Quality Standard Accreditation process. We acknowledge and share Congressional and CMS interest in ensuring Medicare beneficiaries receive high quality care, supplies, and service. We are equally committed to ensuring that patients have access to the care and supplies that they need in a safe, efficient, and timely manner. Unfortunately, our members are finding it increasingly difficult to participate as DMEPOS suppliers.

As I mentioned, the provision of these items is limited by law and the type of medicine that orthopaedic surgeons practice. Therefore, in most cases orthopaedic surgeons are submitting claims for a very small number of DMEPOS items. However, in order to go through the accreditation process, physician practices will be charged approximately $3,000 *per location* to be accredited as having met the Quality Standards. This only makes it increasingly difficult for physicians to participate, especially in the context of impending cuts in payments for physician services and rising costs of providing care. We

have spoken to some small practices that provide so little in terms of DMEPOS that total Medicare claims for the year are only $1,500- yet for those patients who need these items, it is a critical service. I suspect for some practices, that number is even lower. Ultimately, this process will result in a net loss for many physician practices, many in rural areas, across the country.

We believe that this requirement is duplicative of other training that health care professionals, particularly orthopaedic surgeons, receive and that these new requirements are financially and administratively burdensome. This will undoubtedly result in many physicians no longer providing these services to their patients which would adversely impact patient care.

THE IMPACT OF COMPETITIVE BIDDING ON PHYSICIAN-SUPPLIERS

This leads me to the specifics surrounding the competitive bidding program. While *all* physicians who also function as DMEPOS suppliers are subject to the Quality Standards and the accreditation process- for some products, physicians will also be required to submit bids against much larger organizations whose primary reason for existence is the provision of DMEPOS.

Using the public comment period, we expressed our concerns to CMS that the costs and burden associated with competitively bidding for certain products that are so small to the

overall practice of orthopaedic surgery- yet so integral to patient care when utilized - were making physician participation as DMEPOS suppliers untenable.

We would like to applaud CMS for their decision to exempt physicians from having to competitively bid DME that we are allowed under Stark to provide- including crutches, canes, walkers, and folding manual wheelchairs. These items are so integral to a patient's ability to safely leave the site of care that the ability to provide these items should not be impeded by requiring physicians having to submit a bid against much larger organizations that provide these items en masse.

We are, however, extremely dismayed regarding one other category of products subject to the competitive bidding program- and that is "off-the-shelf orthotics." I previously mentioned that orthotics are typically referred to as leg, wrist, back, and neck braces. Congress went on to further define "off the shelf" as orthotics "which require minimal self adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual."

In the final rule where CMS published the physician exception for crutches, canes, walkers, and folding manual wheelchairs, they went on to create a separate exception from the competitive bidding process for off-the-shelf orthotics- but only extended the exception to occupational and physical therapists. In creating the exception, CMS

acknowledged that these items are integral to care, thus necessitating the exception- but in what we believe to be a glaring omission did not include *physicians* in the exception.

In this area, it is not a question of CMS authority. We believe that in the DMEPOS market, orthopaedic surgeons will almost universally be considered small suppliers. And the statute mandating the competitive bidding program *requires* that the "Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program."

Many patients require immediate access to these items for immobilization, injury support, facilitation of safe mobility, or post-surgical recovery. It is unsafe and clinically inappropriate to delay a patient's access to items such as orthotics or to send a patient out of a physician's office without the necessary DMEPOS. We are hard pressed to understand why CMS would believe it necessary to create the exception for therapists, but not physicians.

Recommendations

Finally, I'd like to leave you with a few recommendations regarding physician provision of DMEPOS in the Medicare program which will ensure patient access to necessary items while maintaining the integrity of the program, which I know is a goal shared by all of the stakeholders you've heard from today.

First, regarding the Quality Standards and accreditation, we'd seek your support in recognizing that physicians are already trained to provide and administer DMEPOS to patients. AAOS continues to work with CMS to assure quality in the Medicare program. We firmly believe that, given the complexity of today's health care environment, steps must be taken to ensure that there are not unnecessary or duplicative efforts required of program participants that would discourage patient access to care. In terms of providing public confidence that the providers and suppliers of orthotics are trained and qualified, we believe that professional society credentialing and training processes and state regulation of practitioners already provide many of the necessary safeguards in this area. While we understand the need for a process of this nature, **we ask *not* that physicians and health care professionals be exempted from having to be accredited, but rather- that they be deemed as having met the requirements of accreditation once they are licensed or credentialed to practice medicine under state law.**

In the event that this is not a possibility, **we ask for a delay in the accreditation deadlines for new and existing suppliers**, so that a more coherent set of Quality Standards can be applied to physicians and health care professionals, recognizing fundamental differences between physicians and health care professionals that supply patients DMEPOS during the course of care and retail DMEPOS suppliers.

Finally, with regard to the DMEPOS competitive bidding program- our recommendation is simple: that **physicians be added to the already existing exception for off-the-shelf**

orthotics. Failure to exempt physicians from having to competitively bid to furnish off-the-shelf orthotics to their patients could cause significant access and patient safety issues. Because no off-the-shelf orthotics were included in the list of products to be competitively bid in the first two rounds of the program, there is still an opportunity to remedy this omission before physicians are unable to provide the products to the patients who need them in a safe, efficient, and convenient environment.

SUMMARY

The quality and accreditation requirements applicable to physicians and health professionals should balance the costs of compliance against the affected physician-suppliers' potential for covering these costs. If physicians cannot cover the costs of DMEPOS participation, we run the risk of discouraging participation by small physician practices and reducing patient access to items essential to quality medical care. The ability of a physician to address a patient's condition *during* the physician-patient visit and to ensure that the patient has received the appropriate DMEPOS with proper instruction on its use and application is integral to the quality and efficiency of patient care. However, to require a patient to go elsewhere to receive products that could otherwise have been delivered in their physician's office may lead to disjointed care without the input or expertise of the treating physician.

I would like to thank you, Chairman Shuler, ranking member Fortenberry, and members of the Subcommittee for the opportunity to speak to you this afternoon.

House Committee on Small Business Subcommittee on Rural and Urban Entrepreneurship

May 21, 2008

Competitive Bidding for Durable Medical Equipment

Testimony of Dr. Jon R. Einfalt, PharmD, RP

Thank you, Chairman Shuler and Ranking Member Fortenberry for allowing me to share my thoughts on CMS's competitive bidding process for durable medical equipment. I appreciate this opportunity to share my impressions on this change in the Medicare program.

My name is Dr. Jon Einfalt and I am a pharmacist/owner along with my wife, Dr. Michelle Ernesti-Einfalt, PharmD, RP, and partners, Dr. James Perry, PharmD, RP and his wife Judy Perry, of Tom's Rexall Drug, a small, independent, rural pharmacy located in West Point, Nebraska. I am a third-generation pharmacist and my wife is a second-generation pharmacist. All of that experience is in rural Nebraska. West Point is a small town in northeastern Nebraska and a part of Congressman Jeff Fortenberry's district.

Tom's Rexall Drug provides the West Point area with complete prescription services; drug information services; unit-dose prescriptions for the assisted living facility in West Point; compounding; durable medical equipment (DME) and supplies; over-the-counter (OTC) medications; consulting services for Franciscan Care Services Hospice; and pharmacy staffing for St. Francis Memorial Hospital in West Point. We have 10 full and part-time employees and our professional staff earns approximately 20% less than the current average salary for pharmacists in the Midwest. The building our store is located in has been an independent pharmacy, under several names and owners, for over 100 years. We have a higher concentration of elderly patients than other parts of Nebraska; therefore, our volume of Medicare/Medicaid business is slightly higher than the average of 40%. Last year we had a net profit of $20,000 on sales of $2.375 million. This was slightly worse than the average net profit of 2-3% of sales for an independent pharmacy.

There are approximately 23,000 independent pharmacies located across the country. Many are located in rural areas. This is the case in Nebraska, and many of these pharmacies represent the only healthcare available in their community. Currently

Nebraska has 19 of 93 counties without a pharmacy. Unless some changes start taking place, this number will certainly increase.

In the day-to-day care of my patients, I sell durable medical equipment (DME) and supplies like canes, walkers, diabetic testing supplies, and nebulizer drugs. These products are the tools patients use to treat their chronic diseases and improve their quality of life. For years my patients have depended on me to provide these products and the education necessary to use them properly and effectively. Independent pharmacies have handled sales of DME for decades. Their sales volumes vary tremendously, but their average DME business is about $280,000. My business is much smaller, so my sales run in the $50,000 range. The majority of my sales involve diabetic testing supplies and nebulizer drugs. Even before the implementation of competitive bidding, CMS controlled the reimbursement for these items. In fact, the reimbursement for diabetic testing supplies has not changed for several years. In addition, CMS has greatly curtailed the ability of independent pharmacists to provide some of these vital supplies to patients by setting reimbursement rates well below the acquisition costs of the supplies.

Competitive bidding was introduced by CMS as a tool to control costs. I believe the rules and regulations CMS has implemented with this program will eventually have the exact opposite effect, and costs for this program, other government healthcare programs, and out-of-pocket expenses for my patients will actually increase. The increased costs and significant administrative burden associated with competitive bidding and accreditation will eliminate rural independent pharmacies and other small suppliers from the program. In addition, accreditation will cause hundreds, if not thousands, of small, rural independent pharmacies to close. Competition for supplying DME will decrease and the cost of DME will start to increase. Rural jobs will be lost. Patient access to healthcare will be limited. The 20% portion that patients pay out of their pockets for DME (some patients pay 100%) will increase. To save money, patients will

stop using their durable medical equipment and supplies. Hospital and long-term care visits will increase, and the small savings garnered in the first few years of the competitive bidding program will be quickly lost due to increased utilization of these higher cost healthcare facilities. (This does happen. I can think of several instances like this, involving my patients, in the last year.) This is not a new patient behavior or economic concept. We have seen this exact healthcare scenario played out before.

For the purposes of this discussion, lets look at blood glucose testing strips. They represent approximately 60% of my DME sales. Through a complicated and sometimes impossible process of contracts and rebates, I can buy testing strips from the manufacturers for $22 to $29 per box of 50 strips. CMS currently reimburses patients or pharmacists $33 per box of 50 strips. Last year I sold approximately 250 boxes at $22 cost and 600 boxes at $29 cost. That makes a gross profit of $5150 on $28,000 in sales. Remember that profit number; we'll watch it disappear in a minute. Blood glucose testing is a relatively simple process, and modern equipment is fairly user friendly. However, seldom does a week go by that we are not helping a patient deal with a blood glucose testing issue. These patients are confused about equipment operation and procedures, and some of them have been testing for a number of years. All of these contacts require face-to-face interaction and hands-on equipment. I cannot remember the last time I was able to resolve one of these issues over the phone. Some of these patients receive their supplies through the mail, so obviously the mail order supplier was unable to resolve the issue. In fact, some of these suppliers tell their customers to take their equipment and their problem to their local pharmacy and have us resolve it for them. Pharmacists routinely provide this type of valuable consultation, often at little or no cost to the patient. That will be difficult when we are not around anymore.

Getting back to the numbers --- the costs in time and money to implement competitive bidding and accreditation are prohibitive for small, independent pharmacies. Estimates by CMS, the

associations to which I belong, and the buying and contracting organizations with which I'm involved provide the following projections for participation. Costs associated with preparing and placing a bid are approximately $2000, and I have not seen any estimates of the time involved. Costs associated with obtaining a $65,000 surety bond are about $2000. The cost simply to obtain accreditation from one of the CMS approved accrediting organizations and a Part B supplier number is estimated to be from $4000 to as much as $20,000, with a time commitment over the six month period leading up to the actual site survey of 200 plus hours. These are not one-time costs. Most of them repeat at one to three year intervals. Most rural, independent pharmacies are single owner operations. I don't know how they are going to find the time to prepare for and implement accreditation. Remember my gross profit number from above? If I'm going to see that number decrease because of competitive bidding, then you can understand that I will not be seeking accreditation or selling any durable medical equipment.

There is, however, a more ominous and perhaps catastrophic problem looming here. It comes from the pharmacy benefit managers or PBMs. Their smiles must be large and numerous. If CMS requires accreditation to participate in Medicare Part B, then the next contract I have to sign with the PBMs to fill prescriptions for Medicare Part D (and more than likely all the other commercial insurance plans) will require accreditation. 93% of the prescriptions I fill are governed by a PBM contract. Say goodbye to Tom's Rexall Drug. What the PBMs could not do through their own rules and direct competition, the government is going to do for them.

Pharmacies in Nebraska are licensed and inspected by the State of Nebraska on an annual basis. Pharmacists are also licensed by the state. Both are governed by a comprehensive set of rules and regulations overseen by the Nebraska Department of Health and the Nebraska Board of Pharmacy. I do not need federal accreditation to practice pharmacy or sell durable medical

equipment and supplies. It adds nothing to the quality of the pharmaceutical care I provide my patients. I could negotiate that section out of future contracts, but as an independent pharmacy, the chances of that occurring are not real. Without Congress acting to give business negotiation capabilities to small pharmacies by passing legislation like HR 971, my ability to negotiate fair contracts with giant PBMs is non-existent.

So where does this leave the patient, my patient, your constituent? As you consider the testimony given today, think about the patient first, just like pharmacists and healthcare workers do everyday. A misguided plan to produce some short-term savings in DME costs has suddenly changed into a plan that decimated the access to quality healthcare for rural Americans and increased the overall cost of healthcare for the government. A mailbox is not a pharmacy. Pharmaceutical care cannot be delivered to a mailbox or provided over the phone. It takes contact with patients to be done correctly. If a patient needs an antibiotic, pain medication, insulin, asthma medication, or even a blood glucose testing strip, whether it's a new need or he/she forgot to re-order the product, they can't wait three to ten days to get it in the mail. That means a drive, sometimes a long drive, or doing without. That certainly does not provide an improved quality of life, and unfortunately, in some cases it will mean something much worse.

The June 2008 issue of Consumer Reports once again shows independent pharmacists at the top of the ratings. Rural American pharmacists are independent pharmacists. The Consumer Reports article also has some warnings. Independent pharmacies are under the gun and may be a dying breed. It began a decade ago with the rise of the PBMs and their low reimbursements and continues now with the government and its increased volume and slow reimbursements for Medicare Part D. Independent pharmacies need help from Congress and we need it now. We need HR 1474 so that we are paid promptly and HR 971 so that we have true negotiating power, and we need Congress to tell CMS to fix this

mess involving competitive bidding and accreditation. The drop-dead date (not my term, but interesting considering the situation) for accreditation is September 30, 2009. Many PBMs and other private insurers may soon adopt the Medicare accreditation requirement. Early statistics from the first round of competitive bidding show the scenario I have outlined is already underway. Less than 40% of the suppliers that CMS projected would submit bids actually did. The actual participation of independent pharmacies, as a percent of CMS projections, appears to be much worse.

Ladies and gentlemen, we're going to need your help on this one. Rural, independent pharmacies cannot change these rules or absorb the costs. The high costs of participation and the problem of accreditation must be fixed before this program is expanded. There is little or no cost to the government to fix these problems. The government already controls the cost of durable medical equipment and supplies.

Thank you for inviting me to participate in your discussions. I hope the information I have provided will be useful as you move forward.

HOUSE SMALL BUSINESS

SUBCOMMITTEE ON

RURAL AND URBAN ENTREPRENEURSHIP

MAY 21, 2008

STATEMENT BY

LINWOOD A. STAUB

PRESIDENT, GLOBAL V.A.C.® THERAPY, Kinetic Concepts, Inc. (KCI)

ON BEHALF OF

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

Mr. Chairman and distinguished members of the Subcommittee, on behalf of the Advanced Medical Technology Association, AdvaMed, I thank you for holding this hearing on the Medicare Part B competitive acquisition program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

As you may know, AdvaMed represents over 1,600 of the world's leading medical technology innovators who manufacture over 90 percent of the life-enhancing medical devices, diagnostic products, and medical information systems purchased annually in the United States and nearly 50 percent of the medical technology products purchased globally. Many of the technologies developed by AdvaMed companies have significantly improved the quality of care provided in outpatient settings under Part B and, by doing so, have reduced the need for and cost of more expensive institutional care. Advanced medical technologies today are not only making life better for patients through faster recovery and better outcomes; in many cases, advanced technologies are also saving money for taxpayers. It is also important to note that over 70 percent of our members are relatively small companies with sales of less than $30 million per year. The company I work for, KCI, although a medium size company today, started as a small, family-owned business thirty years ago. We understand how small business drive progress.

Medical technology research and innovation conducted by both large and small companies help drive improvements in the effectiveness and efficiency of our health care system. That is why, as the leading trade association representing manufacturers of innovative medical devices and device-based therapeutic systems, we appreciate the opportunity to share our concerns about the impact of the upcoming durable medical equipment competitive bidding program on outpatient device manufacturers and the patients they serve.

DMEPOS Is Valuable to Beneficiaries and Medicare

For a Medicare beneficiary, access to quality DMEPOS and related services can often mean the difference between remaining at home and admission for institutional care. Twenty-five years ago, DMEPOS was comprised primarily of simple products used to improve the

functional status of patients or to treat relatively uncomplicated conditions. Today, however, sophisticated medical devices used to treat complex conditions in highly compromised patients have migrated safely and effectively from institutional settings into home care. Additionally, advanced diagnostic equipment provides clinical data previously only available through professional laboratories. This evolution of DMEPOS from simple to complex products has improved both clinical and economic outcomes for patients and payers alike.

Competitive Bidding Does Not Appropriately Address Complex Technologies

Unfortunately, the current DMEPOS competitive bidding program has failed to address the fact that there are fundamental differences between simple functional products on the one hand, and diagnostic or therapeutic devices, on the other. Let's take walkers and hospital bed frames as an example. The intended use of these products is to provide support to beneficiaries with mobility limitations. There is little, if any, clinical efficacy research required for these products; and minimal patient and caregiver education necessary to ensure their safe and effective use.

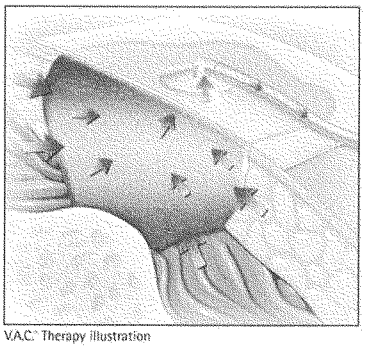
Conversely, therapeutic products like Negative Pressure Wound Therapy (NPWT) systems, which are prescribed for treatment of complicated wounds, frequently occurring in highly compromised patients, require extensive clinical efficacy research and intense levels of support for both patients and their clinical caregivers. Misuse or failure of these therapeutic products could result in serious, potentially life-threatening complications. Because the intended use, clinical evidence requirements, and service needed for therapeutic products are very different from those of simple functional equipment, the DMEPOS competitive bidding program should have, but did not, reflect those differences in four important areas: selection of products for bidding; clinical support and patient education; supplier capacity and capability; and impacts on patients and total Medicare spending.

1. Selection of product categories and codes for bidding:

Therapeutic products deliver clinical outcomes and, therefore, codes selected for bidding should include products of comparable clinical effectiveness. However, some of the codes CMS

selected for bidding include products with wide ranges of quality, functionality, and clinical application. Categories such as Group 2 support surfaces, enteral nutrition pumps, and negative pressure wound therapy systems include such a wide range of products that bidding cannot be the "apples to apples" comparison that was intended by Congress when this program was authorized. Since price is the primary determining factor in selection of winning bidders, the less expensive products at the bottom of the price range are likely to replace the products in the top of the price range, which are the ones prescribed most frequently today. It would be like including four wheel trucks and eighteen wheel trucks in the same bid process using price as the basis for determining winning bidders. In that case, it's unlikely that eighteen wheel trucks would continue to be available and you would no longer have the ability to transport large, heavy loads. In the case of DMEPOS competitive bidding, a similar shift in product availability could mean that the products necessary for the most compromised patients would no longer be available, leading to poor health outcome and increased treatment costs.

As an example, I'll use KCI's V.A.C. Therapy system. V.A.C. Therapy creates an environment that promotes wound healing using three components that work together: a negative pressure pump, an environmentally safe collection canister and a unique foam dressing which is packed into the wound and covered with transparent film. When the pump applies controlled negative pressure to the wound site, the foam dressing compresses in a way that looks a lot like "shrink wrapping" of food. (See Attachment A.)



V.A.C.® Therapy illustration

This compression of the foam dressing under controlled negative pressure provides three important benefits for wound healing:

First, unhealthy fluids and bacteria are pulled out of the wound and into the collection canister. With the excess fluid removed, blood flow to the cells is improved. With the bacterial counts reduced, infections can be prevented or treated more effectively. In other words, V.A.C. Therapy helps remove all of the substances which impede wound healing.

Second, V.A.C. Therapy creates a uniform pressure that pulls the wound edges to the geometric center of the wound — we call this "macrostrain" — which helps to reduce the overall size of the wound and encourages new tissue to grow back in the shape of the original tissue.

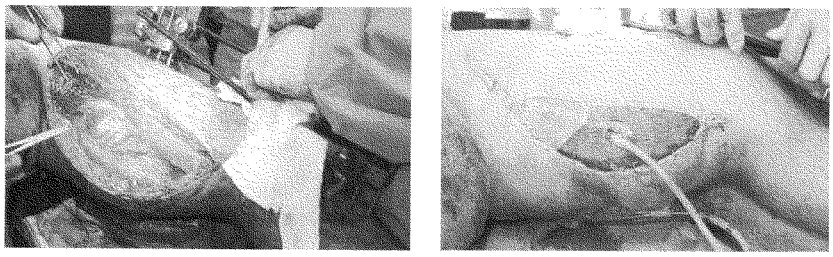
The third benefit, which is truly unique to V.A.C. Therapy because of the unique properties of the foam dressing, is the ability to provide a controlled stretch of individual cells lining the wound, triggering a series of biochemical reactions which cause the cells to divide and replicate more quickly – we call this "microstrain." This cellular stimulation occurs only with V.A.C. Therapy's special foam dressings and the patented pressure sensing technology allows the pump to monitor the amount of pressure at the wound site. There is no evidence that other products currently assigned to the NPWT HCPCS are capable of providing this cellular stimulation or the same rapid wound healing documented with V.A.C. Therapy.

It is also important to note that although V.A.C. Therapy was cleared by the FDA in 1995, CMS, then HCFA, did not cover it until 2000, stating that the level of evidence for the 510(k) clearance did not meet their requirements for establishing either clinical efficacy or safety in the home. However, CMS recently assigned other products to the NPWT HCPCS codes using only the FDA clearances without requiring any evidence of clinical effectiveness or safety in the home.

Since the FDA first cleared V.A.C. Therapy in 1995, nearly two million patients have been treated with the device in U.S. hospitals, long-term care facilities and homes, including

more than three hundred thousand Medicare Part B patients. V.A.C. Therapy has the largest body of clinical evidence of virtually any wound care product with 15 randomized controlled clinical trials, more than 400 peer-reviewed journal articles, six clinical practice guidelines, and 62 textbook citations. V.A.C. Therapy is used to treat a wide variety of acute and chronic wounds and is the only product cleared by the FDA specifically for use in the home.

Outside of Medicare, V.A.C. Therapy is used extensively to treatment war wounds caused by improvised explosive devices. Data published by military physicians from the hospital in Balad, Iraq in 2006 showed that the rate of infections in these types of wounds was decreased from 80% to 0%, and treatment time was reduced from 83 days to 4 days, significantly increasing the limb salvage rate. (See Attachment B.) For this reason, KCI was asked to flight certify V.A.C. Therapy to assist in transfer of these patients from the combat theater to medical facilities in Europe and the United States.



Before and After: V.A.C. Therapy placed on leg trauma wound (IED injury);
Air Force Theater Hospital, Balad Air Force Base, Iraq.

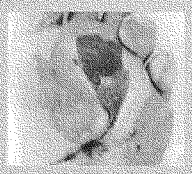
For Medicare Part B beneficiaries, V.A.C Therapy is more often used to treat complex chronic wounds occurring in compromised patients. Because V.A.C. Therapy is the only device proven effective in growing tissue over bone and tendon, it is used frequently to salvage limbs of diabetic patients. V.A.C. Therapy is also effective at healing the most serious types of pressure ulcers in immobile, bedridden patients. A retrospective comparison of V.A.C. Therapy patients managed under the Medicare home health benefit showed that compared with patients

experiencing similar wounds, V.A.C. Therapy patients had lower rates of hospitalization and need for emergent care, as well as improved pain and increased rates of ambulation when compared to patients who were not treated with V.A.C. Additionally, Patients treated with V.A.C. in the home care setting had average cost savings from $3,600 to $12,000 per patient. The average inpatient cost savings ranged from $950 to $31,000 per patient.

Diabetic Foot Ulcer Case: A 53-year-old male with Type-2 diabetes presented in a tachycardic, febrile, obtunded state with a white blood cell count in excess of 25,000 cells/cm.³ Bedside I&D resulted in removal of a large carpet tack from the bottom of his foot.

24 hours post-op: V.A.C.® Therapy applied at its standard (-125 mmHg) intermittent setting for this case, using a V.A.C.® GranuFoam® Dressing.

72 hours post-op: 2 days of V.A.C.® Therapy shows improvement.



120 hours post-op: After 4 days of V.A.C.® Therapy (immediately following this photo), biotissue was applied.

240 hours post-op: After 9 days of V.A.C.® Therapy, V.A.C.® Therapy was discontinued and a moisture retentive dressing was then used to support the bio-engineered tissue construct.

As with any case study, the results and outcomes of this patient should not be interpreted as a promise, representation, or warranty of similar results. Results may vary depending on the circumstance.

Genecov, D. G., et al. A controlled sub-atmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. *Annals of Plastic Surgery*, 1998; 40(3): 219-25.

Case study: Diabetic foot ulcer healed in 9 days, using V.A.C. Therapy

Today, physicians prescribe V.A.C. Therapy to improve clinical outcomes, salvage limbs, reduce the need for institutional care and allow ambulatory patients to be treated while maintaining a normal lifestyle. As a result of the new competitive bidding program, beginning July 1st of this year, V.A.C. Therapy will no longer be available for Medicare Part B beneficiaries in any of the 10 Competitive Bidding Areas for a period of three years because of the methodology CMS used to bid this category.

Individual clinicians and medical societies, including the two largest wound care professional groups in the US, told CMS that other products assigned to the Negative Pressure Wound Therapy codes were not clinically equivalent and, for that reason, this category should not be competitively bid. (See Attachment C.) They also described the serious, potentially life-

threatening consequences of restricting patient access to effective NPWT products, such as a reduced risk of secondary amputation (4% with V.A.C. compared to 10% in the control group). Had CMS used an outside clinical panel to solicit feedback about the product categories and codes they intended to bid, feedback would have supported the removal of NPWT from bidding until clinical comparability of products in the NPWT codes could be validated.

Members of Congress have also challenged the appropriateness of the decision to include NPWT in the current round of competitive bidding, but to date CMS has not answered the questions raised about the lack of clinical comparability in this category.

Our recommendation: with outside clinical panels relevant to the products being reviewed through an outside clinical expert panel. We believe this problem could have been avoided if stakeholders had been given the opportunity to comment on product categories and codes in advance. We urge Congress to direct CMS to allow for such public comment on the categories and codes proposed for all future phases of the DMEPOS competitive acquisition program. We believe that CMS should also convene a meeting of the Program Advisory and Oversight Committee (PAOC) to discuss the categories and codes as well as accept written comments from clinical experts and stakeholders. All of the input received should be taken into account in making final determinations about product categories and their component codes. CMS should also be required to provide a written rationale for final determinations and to respond to all comments received.

2. Clinical support and patient education:

Patients using diagnostic and therapeutic equipment must be educated to ensure that the products are used safely and effectively. It is also important that patients and caregivers have access to appropriate levels of clinical and technical support 24/7 to assist if product problems or clinical complications arise. Without good clinical and technical support, the health and well-being of patients using these products could be jeopardized. For these reasons, CMS should have, but did not, develop product-specific supplier quality standards, specific to each therapeutic product category, except for three categories: respiratory products, complex rehabilitative wheelchairs, and orthotics (which latter item is not included in competitive bidding). NPWT is one of the most complex DME products used in the home setting, and it is

used to treat some of the most compromised patients. Yet there are no quality standards specific to suppliers of NPWT.

Our recommendation: Outside expert opinion and public meetings should be used to identify the need for and develop supplier quality standards specific to individual therapeutic product categories when appropriate.

3. Validating supplier capacity and capability:

For complex product categories, selection of contract suppliers should be based not only on their ability to acquire these products, but also on their ability to provide the support services necessary to ensure safe and effective use. CMS should have, but did not, confirm that all winning suppliers of therapeutic products had both necessary product capacity and support capability. For example, over the past few weeks, KCI has received calls from winning NPWT suppliers who have no previous experience with this product category. Here are a few examples:

- One call came from a winning bidder who does not currently have any NPWT therapy products, and is now trying to determine how he will provide the therapy. He is also trying to figure out how to set up a wound care program from scratch to support what he now believes are challenging clinical and customer service responsibilities that come with these products and patients.
- We learned of one national medical equipment company to whom CMS awarded a contract to supply NPWT in all of the first 10 competitive bidding areas, even though they have never provided these products anywhere. They knew so little about the requirements of the category that they asked us whether a physician's prescription is required for NPWT – it is.
- Another call came from a supplier who had no prior experience but was awarded contracts in the two Florida competitive bidding areas. He offered to sell us his company – along with the contracts.
- Finally, one supplier told us his NPWT therapy bid was a "shot in the dark," because he has very minimal experience with the products.

Clearly, CMS failed to ensure adequate supplier product and support capability in the NPWT category before it awarded contracts. While CMS' approach may be appropriate with simple functional equipment like walkers or wheelchairs, it raises serious questions about whether

patients will have access to both effective NPWT products and appropriate levels of service and support when the program goes into effect.

Our recommendation: For therapeutic product categories, CMS should validate winning suppliers' capacity to acquire the products and capability to support patients and caregivers using those products by developing supplier quality and accreditation standards for those categories.

4. Impact on patients and total Medicare expenditures:

Changes in therapeutic product availability occurring as a result of competitive bidding could impact clinical outcomes and total Medicare treatment costs. For that reason, assessment of the impact of competitive bidding on therapeutic product categories must include comparison of clinical outcomes and assessment of the effect on other Medicare costs. When asked about their plans for monitoring these important metrics, CMS officials have repeatedly said that they do not plan to look at either clinical outcomes or the impact on total Medicare treatment costs. If effective therapeutic products are not available and clinical outcomes are compromised, Medicare Part B savings could be offset by increases in other Medicare costs related to unnecessary or extended hospitalizations (reduced by 26 percent with V.A.C. used in dehisced sternal wounds), increases in emergent care, and prolonged treatment times.

Our recommendation: Congress should direct CMS to evaluate the impact of competitive bidding of therapeutic products based on clinical outcomes and total Medicare costs.

5. Required Bidding Process for Expansion.

We have strong concerns about CMS's ability to use bid amounts determined in setting payments in an MSA (that is a CBA) to set rates in another (non-CBA) MSA. Patient needs and costs for providing care and technologies are not the same in every MSA. If this program continues, CMS should be required to conduct a separate bidding process in each and every MSA in order to ensure that the payment amounts used by Medicare reflect local market conditions.

Our recommendation: We would, therefore, recommend repeal of the existing statutory authority granted to CMS to forego such separate competitive bidding processes.

In summary, we believe medical devices play an important role in improving both the effectiveness and efficiency of outpatient care covered under Medicare Part B. If programs like DMEPOS competitive bidding fail to appropriately address the quality of products, services, and outcomes of these therapeutic products, the research and development investment required for technology innovation may be unsustainable for many small businesses, who contribute so much to the health care system today. We thank you for your interest in hearing our concerns and look forward to working with you in the future to ensure that technology innovation continues to bring value and positive clinical outcomes to patients, providers, and to the Medicare program.

ATTACHMENT A

V.A.C. Freedom®

PORTABLE THERAPY SYSTEM

The V.A.C. Freedom® System helps heal wounds while improving your patients' quality of life.

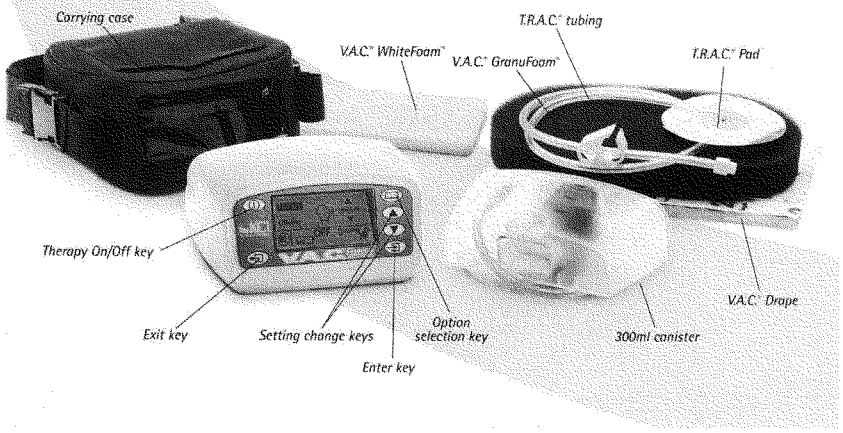
Easy Operation Saves Time

- Large 300ml canister minimizes canister changes
- Canister is easily removed and replaced
- Long battery life – enables patient to be mobile for a full day
- On-Screen User Guide saves time
- New T.R.A.C. Pad® simplifies dressing changes

Greater Patient Comfort

- Lightweight and portable, this system helps patients return to work and daily activities
- Potentially reduces the number of dressing changes and nursing visits over traditional wound care
- Carrying case allows discreet delivery of therapy on the go
- New filter system helps minimize wound odor
- Adjustable rate of dressing draw down for increased patient comfort
- Smart Alarms® help ensure patient safety

At just over 3.5 pounds, the lightweight V.A.C. Freedom® System can be taken almost anywhere and worn in its carrying case over the shoulder or around the waist.



ATTACHMENT B

The Journal of TRAUMA® *Injury, Infection, and Critical Care*

Experience With Wound VAC and Delayed Primary Closure of Contaminated Soft Tissue Injuries in Iraq

Brian E. Leininger, MD, FACS, Todd E. Rasmussen, MD, FACS, David L. Smith, MD, FACS, Donald H. Jenkins, MD, FACS, and Christopher Coppola, MD, FACS

Background: Wartime missile injuries are frequently high-energy wounds that devitalize and contaminate tissue, with high risk for infection and wound complications. Debridement, irrigation, and closure by secondary intention are fundamental principles for the management of these injuries. However, closure by secondary intention was impractical in Iraqi patients. Therefore, wounds were closed definitively before discharge in all Iraqi patients treated for such injures at our hospital. A novel wound management protocol was developed to facilitate this practice, and patient outcomes were tracked. This article describes that protocol and discusses the outcomes in a series of 88 wounds managed with it.

Methods: High-energy injuries were treated with rapid aggressive debridement and pulsatile lavage, then covered with negative pressure (vacuum-assisted closure [VAC]) dressings. Patients underwent serial operative irrigation and debridement until wounds appeared clean to gross inspection, at which time they were closed primarily. Patient treatment and outcome data were recorded in a prospectively updated database.

Results: Treatment and outcomes data from September 2004 through May 2005 were analyzed retrospectively. There were 88 high-energy soft tissue wounds identified in 77 patients. Surprisingly, for this cohort of patients the wound infection rate was 0% and the overall wound complication rate was 0%.

Conclusion: This series of 88 cases is the first report of the use of a negative pressure dressing (wound VAC) as part of the definitive management of high-energy soft tissue wounds in a deployed wartime environment. Our experience with these patients suggests that conventional wound management doctrine may be improved with the wound VAC, resulting in earlier more reliable primary closure of wartime injuries.

Key Words: Wound VAC, Delayed primary closure, High-energy soft tissue injury, Iraq, War wounds, Contaminated, Contaminated wounds, Wound management, Military trauma.

J Trauma, 2006;61:1207–1211.

ATTACHMENT C

To: **Senators** Max Baucus, Charles Grassley, Jim Bunning, Pat Roberts
US Representatives Charles Rangel, Jim McCrery, John Dingell, Joe Barton, Pete Stark, Dave Camp, Frank Pallone, Nathan Deal

From: William J. Ennis DO, President Elect AAWC

Cc: Executive Committee, AAWC
Tina Thomas, AAWC Executive Director

Re: Negative Pressure Wound Therapy (NPWT) competitive bidding

The Association for the Advancement of Wound Care (AAWC) has serious concerns regarding the decision to place negative pressure wound therapy (NPWT) into a competitive bidding category. On behalf of the ever-increasing population of patients and care providers in the USA and worldwide who rely on negative pressure therapy technology, AAWC strongly encourages you to delay any decision for competitive bidding of NPWT until adequate scientific validation of any and all competitors can be conducted.

The AAWC (www.aawconline.org) is the largest, not for profit, multidisciplinary wound care organization in the United States with over 1,800 members. Our organization is represented by several healthcare disciplines as well as patients and lay caregivers. As part of our mission to facilitate optimal, evidence based wound care for patients, AAWC monitors and participates in legislative issues that have impact on our industry and membership.

AAWC is in agreement with the concept of competitive bidding and applauds the efforts being made by the government to control the cost of health care. Many of the commodity health care items that are scheduled for competitive bidding should have the desired effect of reducing costs and improving access. However, the decision to select a product or category of products should be made with a thorough understanding about the science and service issues involved, and ultimately, the potential clinical impact of such a decision.

AAWC does not support any company or product, but AAWC does respond to process and legislative issues that impact optimal patient care. The category of negative pressure wound therapy (NPWT) has not achieved commodity status. Currently, only one company (Kinetic Concepts, Inc - 'KCI') has demonstrated a body of evidence to support the mechanism of action and clinical outcomes derived from the use of their product. The issue at hand is not a KCI issue, but rather it is an issue related to fair assessment of an entire product category. This technology is far from a commodity, such as urinals or hospital bedframes, and we believe additional work is needed before a fair, balanced decision can be made.

Although there are now "competitor" products in the arena of NPWT, these companies have not demonstrated scientific evidence to prove equivalency. KCI's NPWT system as been cleared by the FDA as an "integrated wound care system for use in acute, extended and home care settings. V.A.C. NPWT creates an environment that promotes wound healing by decreasing edema, promoting granulation tissue and perfusion, and by removing exudate and infectious materials." It is important to understand that the "pump" component of NPWT systems is only one aspect of the overall product. The foam dressing utilized in the KCI product is also important to its clinical effectiveness. The other systems allow for the use of any dressing based on a clinician's preference or the use of pre-packaged gauze. While there may be future scientific evidence that supports the equivalency of these systems, at the present time there is none. This violates the rule of practicing evidenced based care. In addition, most trauma centers and acute care hospitals rely on this technology for their most compromised patients. Competitive bidding of NPWT could deny access to many Medicare patients who need this therapy to avoid complications, which could result in a significant amount of wasted dollars on ineffective care.

In summary, we respectfully request that you delay any decision for competitive bidding of NPWT until adequate scientific validation of any and all competitors can be conducted. Thank you for your time in reviewing this important matter. I and other members of our Executive Board would be happy to discuss this matter with you. I can be reached by pager number 708-242-0801 or by email at w.ennis@comcast.net.

ATTACHMENT C

APWCA
American Professional Wound Care Association

A Professional Association for Wound Care and the Related Sciences
853 Second Street Pike, Suite #A-1 • Richboro, Pennsylvania 18954
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August 30, 2007

Michael O. Leavitt
Secretary of the
US Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Leavitt,

The American Professional Wound Care Association is a non-profit organization and has approximately 2000 members making it the largest organization of its kind in wound care. Additionally, APWCA membership contains the highest number of prescribing physicians who make up approximately 80% of our members. We are proud to say it is also the fastest growing organization with just six years of operation. The APWCA does not endorse any product and serves as an educational resource so there can be a dialogue between provider and carrier to address items of concern in an unbiased manner.

The APWCA has a concern regarding the allowance of competitive biding for the advanced form of wound care known as negative pressure therapy (NPT). This treatment can be of tremendous benefit to wounds that are often non-responsive to other forms of therapy.

The only long established NPT system was developed by KCI (Kinetic Concepts Inc.). This company developed, manufactures and distributes their NPT system called the V.A.C. (Vacuum Assisted Closure). The V.A.C. system is the only product for negative pressure therapy that has established research and literature which provides a preponderance of evidence to support its efficacy. Over the past few years there have been several other companies that have developed their own NPT systems. There is little evidence to support their use which utilizes different materials and different pressures.

While cost of product is an important issue, it is also true that efficacy is the most important aspect of a form of therapy. There is an old saying "Most expensive device is the one that does not work". In that context APWCA members have found application of NPT other then the KCI-VAC system on specific cases proved non-efficacious, while these same patients had satisfactory results when changed to the KCI system. Indeed, there may be cases where the reverse was true in specific instances. The important point to all this, is that this is an advanced form of therapy that requires meticulous application and high quality of control in the materials. Inconsistency in any of these areas provides a situation that at best is not helpful but at worse causes increased harm through infection, peripheral tissue damage, and other complications.

The Association finds competitive bidding for negative pressure therapy to be inappropriate and may increase risk to patients. Physicians should have the ability to select that form of NPT they feel is best to treat these compromised and at risk patients. Competitive bidding would force physicians to use only one form of NPT therapy as provided by only one company in their geographic area. They would not have the ability to choose the application of NPT that best meets the needs of their patients based on the literature and more importantly based upon their experience and the quality of their patient outcomes. This ultimately could increase risk to patients and increase patient morbidity while subsequently causing unintended demands to the health care delivery system.

The American Professional Wound Care Association respectfully requests that the policy to utilize competitive bidding for Negative Pressure Therapy be reconsidered. The Association beheves this to be inappropriate for this form of therapy. APWCA is available to provide further comment should the need arise.

Sincerely,

David Brotman, MD, FAPWCA
Insurance Committee

June Partyka, RN, CWOCN DAPWCA
Insurance Committee

Steven R. Kravitz, DPM, FAPWCA
Insurance Committee

Hard copy to follow

ATTACHMENT C

July 25, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop C5-11-24
Baltimore, MD 21244-1850

RE: 2008 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Demonstration Project

Dear Administrator Norwalk:

On behalf of the 2300 members of the Society for Vascular Surgery (SVS), we wish to express concerns regarding one specific category of the 2008 DMEPOS Competitive Bidding Demonstration Project that was included in the Medicare Modernization Action of 2003: **Negative Pressure Wound Therapy (NPWT).**

Please note that SVS generally supports the concept of competitive bidding for commodity supplies such as canes, walkers and urinals. Having stated our general support, SVS believes that NPWT exceeds the level of a typical supply and we request that this category be removed from the 2008 Competitive Bidding Demonstration Project.

There is truly extensive scientific literature to support clinical efficacy of one specific NPWT product. The scientific support includes several randomized controlled trials as well as a substantial list of multi-center case studies. While there are other NPWT products, the systems are dissimilar and the scientific literature is relatively lacking.

Vascular surgeons and other providers who rely on scientific evidence to guide their decisions on wound care should not be denied access to a product for which there is an impressive accumulation of evidence. SVS believes that if a provider can base his or her choice of clinical NPWT products on review of substantial medical literature published in peer-reviewed journals, this serves to prove that NPWT should not be considered a commodity supply product.

SVS is aware that the Final Rule has been released and the bid window will close on July 27, but we assume this program will be expanded in the future. We believe that in the nine other categories, which are vastly different from NPWT, competitive bidding will be an effective and appropriate way to use the "marketplace" to make commodity supply products such as canes, walkers and urinals less expensive. However, clinical efficacy is the most important factor for NPWT.

For these reasons, SVS urges CMS to remove NPWT from the 2008 Competitive Bidding Demonstration Project. Please feel free to contact Pamela Phillips, Director of Health Policy and

ATTACHMENT C

-----Original Message-----
From: Boulton, Andrew [mailto:ABoulton@med.miami.edu]
Sent: Wednesday, June 06, 2007 10:04 AM
To: kathy_nuebel@grassley.senate.gov
Cc: lklavery@yahoo.com
Subject: NEGATIVE PRESSURE WOUND THERAPY (NPWT) AND CMS COMPETITIVE BIDDING PROGRAM FOR DMEPOS

Dear Senator Grassley
We are writing to you to request that you take action to remove negative pressure wound therapy (NPWT) from the CMS Competitive Bidding program for DMEPOS. Medicare beneficiaries with serious and complex wounds need access to KCI's V.A.C.® Therapy, and Competitive Bidding puts this access at risk. The potential consequences are severe and limbs and even lives may be at stake.

We are writing as experts in diabetic foot wound care and we represent a large body of opinion across the United States. Diabetes is a major cause of lower extremity amputation and such operations are usually preceded by foot ulceration. As we are sure you are aware, there is an explosion of cases of Type 2 diabetes in our country which is going to lead to further foot problems. We have published widely on the clinical benefits of NPWT in diabetic foot wound management, and 2 randomized trials have confirmed the efficacy of this treatment both in post-operative wounds (published in the Lancet and one of us (Lavery) was a co-author on this paper in 2005) and the other was recently presented at a wound healing meeting in April 2007, held in Tampa, FL. Thus, there is high quality evidence to support the use of this therapy in both diabetic foot wounds and also post-operative diabetic foot cases.

We therefore do not support CMS' recent decision to include NPWT in competitive bidding and would like to stress the following points:
* Products currently assigned to the NPWT category include V.A.C. Therapy and several gauze-based drainage devices. These products are not clinically equivalent.
* V.A.C. Therapy is a unique, highly effective product used to treat many types of complicated wounds in even the most compromised patients.
* V.A.C. Therapy is the only NPWT product clinically proven to reduce wound healing times and complication rates and, therefore, should not be compared to unproven gauze-based wound drainage systems. If access to V.A.C. Therapy is eliminated, CMS would essentially be directing physicians to use products that violate the rules of evidence-based medicine. As stated above, we have provided excellent evidence to support the use of V.A.C. therapy in contrast to the other modalities included under this title.
* Suppliers of gauze-based drainage devices do not provide clinical support services comparable to those provided by KCI.
* Protecting beneficiary access to quality medical devices is one of competitive bidding's main objectives. Eliminating access to V.A.C. Therapy - a potential outcome of the bidding process - is inconsistent with this objective.
* Without V.A.C. Therapy, many patients will suffer serious medical complications, resulting in increased costs for the Medicare program.

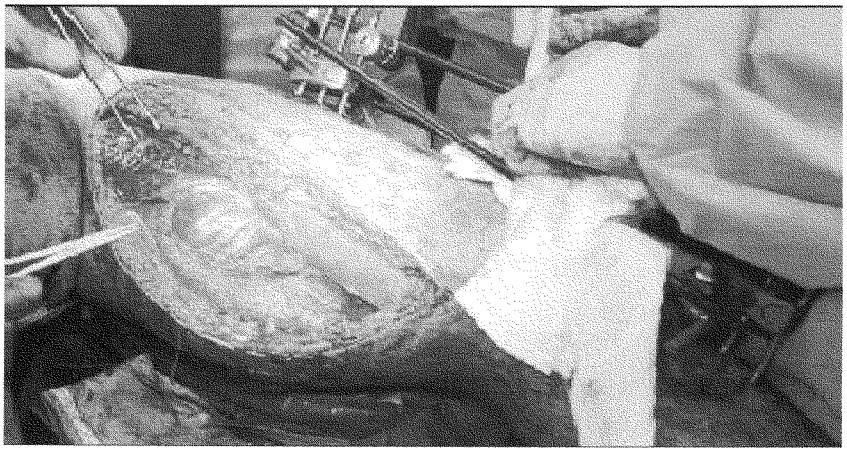
We do hope that you will give serious consideration to the points raised in our letter and that you will encourage the removal of NPWT from the CMS Competitive Bidding program for DMEPOS.

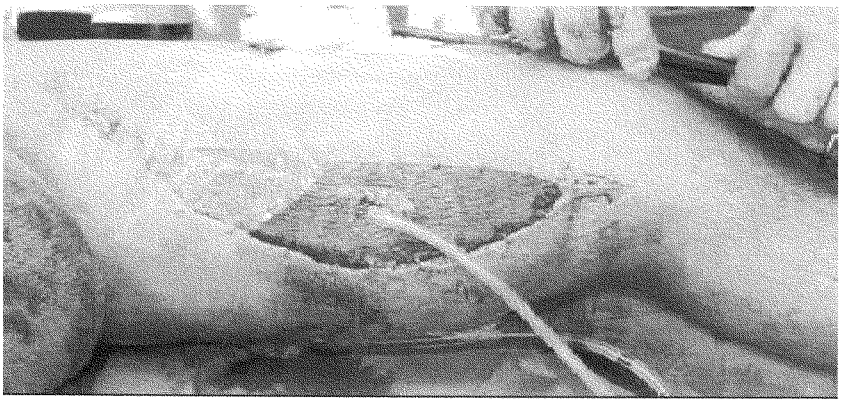
Yours truly

Andrew JM Boulton, MD DSc, FRCP
Chair, Foot Care Interest Group
American Diabetes Association

Larry A Lavery, DPM. MPH
Immediate Past Chair, Foot Care Interest Group
American Diabetes Association

ATTACHMENT D





Left thigh trauma wound
Before and after placement of VAC Therapy dressing
Balad Air Base, Iraq

ATTACHMENT D

Right arm trauma wound
Before and after placement of VAC Therapy dressing
Balad Air Base, Iraq

ATTACHMENT D

House Committee on Small Business
Subcommittee on Rural and Urban Entrepreneurship

"Competitive Bidding for Durable Medical Equipment"

May 21, 2008

Testimony of Mr. Casey Hite
Vice-President, Aeroflow Healthcare
Asheville, NC

Testimony of the
American Association for Homecare
before the
Subcommittee on Rural and Urban Entrepreneurship
of the Committee on Small Business

Competitive Bidding for Durable Medical Equipment

May 21, 2008

Good Morning Mr. Chairman and distinguished members of the Subcommittee on Rural and Urban Entrepreneurship. My name is Casey Hite. I am a small business owner and Vice-President of Aeroflow Healthcare, a small home medical equipment company in Asheville, North Carolina. I appreciate this opportunity to testify before you today, on behalf of the North Carolina Association for Medical Equipment Services (NCAMES), the American Association for Homecare (AAHomecare) and small home medical equipment providers across the nation.

Aeroflow Healthcare is a company that my brother and I founded in 2001. Aeroflow provides oxygen and mobility equipment and services to approximately 13,000 active patients in North Carolina, South Carolina and Tennessee who have respiratory and mobility-related problems. I entered the home medical equipment industry to provide compassionate care to western North Carolina's elderly and disabled population. I decided to enter this industry after visiting my grandmother who was slowly dying from chronic heart failure in a local nursing home. The nursing home was providing her with oxygen from a dilapidated oxygen concentrator that broke down frequently which caused her to have severe anxiety about potentially dying in her sleep. At that time, the only home medical equipment providers in the area were large corporations that were based in Florida or as far away as California. We believed there had to be a better way.

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. NCAMES is the state home medical equipment association representing 250 providers. NCAMES and AAHomecare work to strengthen access to high quality care for millions of Americans who require home medical equipment, services and therapies in their homes. Many of AAHomecare's 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 Asheville, North Carolina area and I have heard and seen in detail Round One 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 AAHomecare predicted based on CMS' failure to recognize and account for the true nature of the way home medical equipment is provided to 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. Such a dramatic reduction in the number of homecare facilities will result in reduced access to home medical equipment providers and the quality of services that they provide if this bidding program moves forward in its current form.

This program will 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 resulting in market concentration rather than a competitive marketplace.

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 18 million, or about half of all Medicare beneficiaries requiring home medical equipment could be affected, that is as many as eighteen million beneficiaries. 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.

Congress must not let this program move forward, in its current form. We urge you to delay 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 delay in the implementation timeline to review serious concerns and examine alternatives, Medicare's home medical equipment benefit will be irreparably harmed.

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. We do not believe that any program where more than 60 percent of suppliers were disqualified should be considered a success. These statistics point to a failure by CMS to educate suppliers properly 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) which we believe led to some suppliers being unable to navigate the program and therefore fully participate in it.

More procedural and operational flaws that threatened the integrity of the entire program became more readily apparent when CMS began informing suppliers of 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 submitted by suppliers properly and in a timely manner; (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 website stated that the CBIC would 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 were observed by suppliers 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 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. The CBIC reneged on this promise sending 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

We believe that the Medicare bidding program will radically change the HME marketplace and dismantle the nation's home medical infrastructure if implemented in its current form. CMS will selectively contract with approximately only 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 was to risk business failure immediately. 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 incorporated into the matrix of pricing. 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. All businesses rely on transparency and clear rules in order to operate effectively. For small businesses, in particular, this is especially critical. 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 as well as how small businesses were expected to compete. CMS' unwillingness to share basic

information about the program raises serious questions about any future rounds with respect to fair supplier selection and patient access to quality suppliers. Their guidance to the supplier community has also been inadequate with an unrealistic timeline and processes to accommodate any transition.

CMS has not shared meaningful bidding data, the methodology and criteria used to establish new Medicare payment rates or 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 market 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 reevaluate 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.

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 27 business days because the program starts on July 1.

In the complex power wheelchair marketplace, there are a number of troublesome 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 guarantee that "winning" suppliers exclusively use 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 as the complex power wheelchairs that are currently provided nor meet all of the beneficiary's needs. 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.

In the diabetic arena, CMS made decisions 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 a competitive bidding area. This was not envisioned by Congress. This 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 where there are no Medicare savings. We believe that CMS should establish one reimbursement rate for a product in a bidding area regardless of where it is purchased, at a fair rate that allows choice so that beneficiaries do not have to switch their products and systems.

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 and who moves to a new geographic area is unlikely to find an oxygen provider willing to furnish him or her with the same level of technology.

There is also the real issue of suppliers being unable 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 must prepare 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 to which patients are accustomed.

My overarching concern with the bidding program is that I can foresee a decline in the quality of equipment and service when beneficiaries change products to generic or less costly items. Beneficiaries will be forced to switch providers with whom they have had a trusted relationship for years. Imagine a child growing up with a disability through to

adulthood who has been using one HME provider his or her entire life, and now, as an adult under the bidding program, must switch to a new provider who is unfamiliar with his or her medical history or specific needs. Items such as oxygen services for a person living with COPD or a customized power wheelchair for a person living with ALS, are not luxury items that consumers are able to live without but instead are essential life-sustaining items and services.

The cost of the medical equipment that we provide is only a fraction of the total cost of caring for a patient. There are additional costs associated with hiring employees, training staff to file insurance claims, training and having licensed therapists on staff, and the costs associated with meeting various federal and state licensing requirements. Suppliers must consider these additional business costs as they evaluate their bids under the competitive bidding program. My company may not be able to continue to provide items and services if we are not a contract supplier and must consider grandfathering patients at the winning bid rate.

As this untested program begins, we must be aware of the enormous real-life impact that this program will have on individuals with significant disabilities such as spinal cord injuries, cerebral palsy, multiple sclerosis and ALS.

Impact on Beneficiary Access to Care

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.

We are 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 likely be overwhelmed by the rush of patients switching 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 are also 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.

Home visits are an important part of the quality service that AAHomecare members provide to their customers, including Medicare beneficiaries, many of whom are homebound. Most Medicare beneficiaries who require power wheelchairs live with long-term debilitating conditions that are not short-term in nature and, with few exceptions, use a power wheelchair for the remainder of their lives. Medicare beneficiaries who require access to appropriate mobility devices rely on their wheelchairs in order to maintain their independence and quality of life. If the new contract provider cannot afford to provide home visits, that consumer must rely on others to drive him or her to the new provider. That new provider may be great distances away.

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 27 business 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 who 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.

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 delay the implementation of this bidding program. We support 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 Subcommittee and other members of Congress to address these complex challenges and ensure the provision of cost-effective and quality homecare to deserving Medicare beneficiaries.

MOUNTAINEER OXYGEN SERVICES, INC.

House Committee on Small Business
Subcommittee on Rural and Urban Entrepreneurship

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

May 21, 2008

Testimony of Mr. Heath Sutton
President, Mountaineer Oxygen Services, Inc.
Waynesville, NC

On behalf of the

North Carolina Association for Medical Equipment Services

Testimony
of
Mountaineer Oxygen Services, Inc.
before the
Subcommittee on Rural and Urban Entrepreneurship
of the
Committee on Small Business
of the
U.S. House of Representatives

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

May 21, 2008

Good morning Mr. Chairman and distinguished members of the Subcommittee. I am Heath Sutton. I am a respiratory therapist and am the President and founder of Mountaineer Oxygen Services. My home medical equipment practice is based in Waynesville, North Carolina with a branch office in Sylva, North Carolina. My wife and I started our home medical equipment company to focus on the care of homebound oxygen patients and patients with sleep disorders.

Our company was founded to meet the needs of patients in a small town environment. We are slated to be in Round Two of the Medicare bidding program based on the location of our practice. Having seen the devastating results that this program has caused in Round One, we are desperately concerned about its impact on both small providers like ourselves and the patients we take pride in serving.

We began our company with the motto "Treating Patients Like Family". This motto is printed on our forms and is painted on our company delivery vehicle. Since founding our practice over five years ago, we have consistently devoted ourselves to meeting this standard. Throughout our history we have been proud to serve the needs of Medicare beneficiaries and these patients have always represented about 75 percent of our business.

My wife and I are proud examples of the American dream since we founded and built our own business. We recognize that health care costs are escalating and fully appreciate the efforts of our government to gain control over the expanding costs of government programs, including Medicare.

However, I am not convinced that the recent changes implemented by Medicare, given the misleading name of "competitive bidding," will accomplish either lower

overall costs nor strengthen health care for our elderly and disabled members of the population. Instead of increasing competition, this new program will result in market concentration with only a few home medical equipment providers.

The first phase of program implementation has illuminated serious difficulties with the program. If the goal of the program was to provide better care at lower prices, I strongly believe that those changes will do neither.

The most serious problem we see is the lack of access of patients to quality health care. Results from Round One of this program have clearly shown that nearly 2 out of every 3 providers, although fully accredited and currently serving the market, were disqualified from participation. Based on CMS' own calculation of the number of home medical equipment providers in the 10 areas subject to bidding in Round One, CMS has chosen to contract with only about seven percent of providers in these areas. This enormous reduction in the number of providers able to serve Medicare beneficiaries for services and items subject to bidding will most certainly result in a large scale reduction of access to quality of care for the majority of Medicare beneficiaries. How will it be possible for the more than 200,000 home oxygen patients to receive proper and acceptable care from less than 10 percent of the current providers?

Furthermore, some of the "winning bidders in Round One gained contracts for geographical areas they have never covered. How can they serve these areas unknown to them and more importantly how can they do so by July 1, 2008, which is when program implementation begins?

There are only two possible options:

1. Quickly open locations inside the new areas and try to staff and supply those new locations within weeks.
2. Subcontract with local providers already inside the new areas.

If the second option is chosen, the bidding program, as currently devised, gives no assurance that the subcontractor will be accredited, which on its face violates the spirit of the recent Medicare change to only approve reimbursements to fully accredited providers that can provide quality care to Medicare beneficiaries.

This flawed program, which will impact an additional 70 MSAs later this year, will again replace currently accredited providers with unaccredited subcontractors serving the beneficiaries. Winning contract suppliers may have never served those patients before and access to quality care for a large number of current patients will be reduced significantly under the bidding program.

Let me share with you an example of the type of patient that will be impacted by this program, We currently serve an elderly patient with severe COPD and chronic hypercapnea, which is an excess of carbon dioxide in the blood. She is

the first oxygen patient that Mountaineer Oxygen Services set up on home oxygen in October 2003. She lives alone and has no family. At least once a week she calls our on-call service between 9-10pm on her way to bed asking for help to attach her water-bottle onto her oxygen machine. She panics when she cannot get her oxygen bottle re-connected and has us on her speed dial. Once a week for the past four years our on-call person knows he must drive out and assist her. Several times she has panicked and been unable to dial our number and calls 911. This patient will suffer emotional stress and potentially serious health consequences if we lose the bid in Round Two, not to mention if the Round Two bidder is over 100 miles away. She relies on us to care for her needs.

We hope that all involved at the Federal level will understand the gravity of the changes that are about to occur in the home medical equipment and service benefit. Small providers who have spent their lives taking the risk to start their own practices and have built their businesses on serving a population base that comprises about 50 percent of Medicare patients may quickly fail due to being excluded from the marketplace. These providers are serious, diligent, hard-working Americans who have been devoted to their Medicare beneficiaries' needs for many years. They are providers who have made substantial investments in both their firms and in accreditation to be qualified to serve Medicare beneficiaries.

The majority of American jobs are created by small businesses, not large corporations. We need these jobs for the U.S. economy in these uncertain times of massive outsourcing of American employment.

In large metropolitan areas, job losses may not be seen as catastrophic, but in a moderately-sized or small town market, as further phases of the program are implemented, small business failures will be significant. Will the larger providers be willing to commute to the outskirts of bidding areas to properly service the needs of those patients at significantly reduced payment rates? If they try to subcontract the work, will profit margins support two companies at the newly established payment rate?

Having seen and heard how Round One has been implemented, I believe that successful bidders submitted unrealistically low prices for products which they have never before provided to the market. These firms have no experience in the provision of these products and services yet their bid prices were used to calculate the new payment rate.

Round Two providers are going to look to the prices established in Round One and make the decision that they must bid below those Round One payment rates to receive a winning contract from CMS. It is a desperate vicious cycle with no winners. Providers will be forced to cut services or the quality of products. There will be wide-scale business failures because suppliers will loose a meaningful

portion of their revenue base. And those who have the most to lose will be patients who have come to rely on their local small provider. They may be required to go to the hospital, call 911 or visit their physician more frequently. None of these costs has ever been considered as part of bidding. This program is not a market-based system that rewards quality and innovation. Instead, it is selective government contracting that may well begin the destruction of our nation's homecare safety net and lead to higher costs.

What also troubles me is my government's seeming unwillingness to share with the public even the most basic information about this program. How were the new payment rates established? What criteria were used to evaluate the financial wherewithal of homecare providers and their expertise in the provision of bidded items and services? These questions are in addition to the fundamental problems of the bidding program which resulted in the disqualification of more than 60 percent of suppliers who tried to participate.

I also find it dangerous to consider that bid pricing could be applied to non-bid areas beginning in 2009. Payment rates established through bidding in Miami or Dallas are not reflective of the cost of business in non-urban areas.

On the oxygen side of the business, the problem has become more complex. Even before bidding was implemented, providers knew that on January 1, 2009, the transfer of ownership of oxygen equipment and the 36-month payment cap will surely bring negative impacts to the patients and providers in the latter months of their 36-month period. Any patient who must change providers late in their period will find it difficult, if not impossible, to find a provider willing to arrange the same level of quality equipment or even modest care for an extremely low return.

Finally, we remain skeptical that the relatively minor savings on the DME products involved (as a percent of Medicare overall spending) has been analyzed thoroughly, with acknowledgement of the added costs to Medicare of patients who may find it necessary to show up at the hospital emergency room to receive care because their local provider no longer can serve them and the subcontractor may be many miles away. Current estimates show that DME outlays by Medicare average around $8 per day. Average emergency room visit costs just over $4600 per day.

I ask the House and Senate to delay this flawed program from proceeding and to work with those of us closest to the markets to arrange a proper program, fair and effectively priced to serve those in greatest need. I would like to remind you that history judges nations not by how they treat their leaders but rather how they care for the most vulnerable in our society.

I thank you for giving me the opportunity to testify before you today.

TESTIMONY OF:

The American Optometric Association

Presented by:

Rebecca H. Wartman OD
Owner, Doctors Vision Center of Asheville
Asheville, NC

House Committee on Small Business

Subcommittee on Rural and Urban Entrepreneurship

Hearing on "Competitive Bidding for Durable Medical Equipment"

Wednesday, May 21, 2008

TESTIMONY OF:

The American Optometric Association

Presented by:

Rebecca H. Wartman OD
Owner, Doctors Vision Center of Asheville
Asheville, NC

House Committee on Small Business
Subcommittee on Rural and Urban Entrepreneurship
Hearing on "Competitive Bidding for Durable Medical Equipment"

Wednesday, May 21, 2007

Mr. Chairman and Members of the Committee:

The American Optometric Association (AOA), representing over 34,000 doctors of optometry, would like to thank the Committee for holding this important hearing. My name is Dr. Rebecca Wartman and I am the owner of Doctors Vision Center in Asheville, NC. As an optometrist and small business owner, I am pleased to have the opportunity to provide witness testimony regarding burdensome requirements established by the Medicare Modernization Act (MMA) in the *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)* and the chilling effect on providing patient care.

The AOA appreciates that the Centers for Medicare and 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 clinicians.

Optometrists and other physicians and health care professionals are concerned with two requirements of the program which, if implemented, 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 eyeglasses/lenses following cataract surgery, off-the-shelf orthotics (OTS), crutches, canes, walkers, and folding manual wheelchairs. 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 or to send a patient out of a practitioner's office without the necessary DMEPOS.

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 a primary part of their businesses. There is also a lack of recognition that health care professionals not only prescribe appropriate 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 providing DMEPOS to the public as a business alone but for the good of their patients, and it is unwarranted and inefficient for further accreditation to be required of them to perform the patient services for which they have been educated, trained, and licensed.

The DMEPOS products provided to Medicare beneficiaries by the roughly 14,000 optometrists with DMEPOS supplier numbers are lenses (Single vision or multifocal) and frames provided to individuals following cataract surgery, and these items are clearly an integral part of what the practice of optometry is all about. As of March 1, 2008, Medicare required health care professionals who are either new to the program or are existing suppliers opening a new practice location to become accredited prior to obtaining a national supplier clearinghouse (NSC) number. This requirement is unduly burdensome and unjust to optometrists 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.

Optometrists and other 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 professionals who only dispense DMEPOS when providing patient treatment.

Accreditation costs as much as $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 optometrists and other health professionals' small businesses that do not, or cannot afford, to hire additional full-time regulatory compliance staff. Out of 10 accrediting organizations, only 4, possibly 5, accredit for post cataract eyewear.

A supplier manual from one of the CMS-sanctioned accrediting organizations 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 these items 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, optometrists and other 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 American Optometric Association has received numerous complaints from optometrists indicating that they will no longer provide this service if they have to become accredited.

With burdensome new supplier regulations, optometrists – as well as a range of other health providers – could be faced with being unable to provide Medicare-covered DMEPOS products to their patients at the point of care. 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. The cost of transportation, the need for at least two trips in most cases – one to select and one to have dispensed, the burden of finding a provider will all be serious hurdles for many Medicare beneficiaries. Likewise, for patients in nursing facilities or assisted living, many of whom I serve, will be faced with having to coordinate transportation and appointments, etc. Another example would be for aphakic patients who require contact lenses to be fitted following cataract surgery; they will face an increased health risk if this service is not performed with care and skill by an optometrist or other licensed qualified eye care provider.

As such an outcome would prove to be harmful to physicians and patients; it must be avoided through revised regulations. A "one size fits all" approach by CMS fails to recognize that DMEPOS suppliers today comprise a very diverse set of individuals and organizations, including licensed health professionals such as optometrists. The AOA believes that the accreditation and quality standards developed by CMS should recognize this diversity and be structured accordingly, and we believe the MMA gives the agency sufficient flexibility to do so.

We look forward to working with the House Small Business 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.

Home Health
Home Medical Equipment
Heart of Iowa Hospice
Community Health

STATEMENT BY

JULIE WEIDEMANN CRT, RCP, BS

DIRECTOR, PALMER HOME MEDICAL SUPPLY

HEARING ON DMEPOS COMPETITIVE BIDDING PROGRAM

BEFORE THE

HOUSE SMALL BUSINESS SUBCOMMITTEE

ON

RURAL AND URBAN ENTREPRENEURSHIP

UNITED STATES HOUSE OF REPRESENTATIVES

May 21, 2008

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INTRODUCTION

Chairman Shuler, Ranking Member Fortenberry, and Members of the Committee, I am Julie Weidemann, Director of Palmer Home Medical Supply. I am pleased to come before this Sub-committee to discuss with you the profound risks of the DMEPOS Competitive Bidding (CB) Program being implemented by the U.S. Department of Health and Human Services.

I am a Certified Respiratory Therapist and an Iowa Licensed Respiratory Care Practitioner. I have worked in the home medical equipment industry since 1988. I started my homecare career as a respiratory therapist and, in 1994, created and instituted Palmer Home Medical Supply, a department of Palmer Lutheran Health Center, Inc., which is a 25-bed hospital in West Union, IA. I returned to college and obtained a business management degree from Upper Iowa University in 2003.

My company, Palmer Home Medical Supply, serves ten counties in rural northeast Iowa, covering 2,500 square miles, close to 50% of my business includes Medicare beneficiaries. We have three locations in West Union, Oelwein, and Sumner. As Director, I oversee a staff of ten employees: three respiratory therapists, one registered nurse, two medical equipment delivery technicians and four customer service/billing staff. According to a study on women-owned businesses conducted by the U.S. Small Business Administration, between 1997 and 2002, the numbers of women-owned firms increased by 19.8 percent and of the number of women-owned employer firms, increased by 8.3 percent. Also, firms owned by women increased employment by 70,000 individuals.[1] Women-owned businesses are a critical part of today's economy and I am concerned that the competitive bidding program will force many of these companies out of business.

Currently, I serve as Vice-President and the Education Committee Chair for the Midwest Association for Medical Equipment Services (MAMES). I am also a member of VGM & Associates of Waterloo, Iowa. I am active regarding legislative issues in the home medical equipment industry and I am very passionate about ensuring the patients I serve receive quality care. I assisted in the creation and implementation of the compliance program for the hospital, and I continue to serve as the Co-Compliance Officer for Palmer Lutheran Health Center. I also oversee all mandatory accreditation activities for Palmer Home Medical Supply.

Concerns with DMEPOS Competitive Bidding Program

In Section 302 of the Medicare Modernization Act (MMA) of 2003, Congress mandated the Centers for Medicare and Medicaid Services (CMS) to include small business protections, however, CMS could not have damaged small home medical equipment (HME) business more if they had tried to do so. The results of the competition are unambiguous proof that CMS not only failed to protect small business but, if not stopped, CMS will decimate the ranks of small HME businesses in a matter of months. At the start of this process it was widely estimated that the HME business sector

[1] *Women in Business, 2006 A Demographic Review of Women's Business Ownership*. Ying Lowrey, Office of Economic Research, Office of Advocacy, U.S. Small Business Administration. August 2006, No. 280.

consisted of over 85% of small business units. CMS created a target set-aside of 30 percent for small businesses. CMS then removed the viability of the only economy of scale available to small businesses that wanted to continue to participate, as demonstrated in the consolidated billing network model, by artificially cutting nearly in half the definition of a small business and prohibiting consolidated billing.

This is a fatally-flawed program and no amount of rearranging the deck chairs will save this Titanic-like scheme, which at its heart, contains an unavoidable downward spiral of desperate bids. As a result, there will be less and less quality in service and products until the bottom is reached and we are left with near-bankrupt providers. The current existing solid core of high-quality and great-service small business providers will be gone and the elderly and disabled will be worse off because of it.

At the top of the CMS rhetoric on this issue is the question of price. The statistic of 26% savings to the program is misleading. Medicare beneficiaries, in part, select their providers for the products, but even more so, for the quality of care and service. Competitive bidding takes this choice away from the beneficiary at a great cost. Please do not move forward with a flawed program that destroys small businesses and takes services away from our patients for the reason of saving money for the program. I do believe that if CMS increased its work in policing the fraudulent providers and banning them from the Medicare program, the cost savings would be substantial. This then allows the small HME business providers to do what we do best - take care of our patients with compassion and great service.

Impact of DMEPOS Competitive Bidding on Rural Providers

Where Palmer Home Medical Supply would have the largest concern over competitive bidding program would be in the MMA 2003 provision that includes the ability of CMS to apply payment rates achieved through bidding to non-bid areas (known as inherent reasonableness authority) to the fee schedule in 2009. This provision allows CMS to take the "savings" that is achieved in desperation bids from Round One and apply pricing nationwide with a new fee schedule. CMS has stated on several occasions that "Competitive Bidding will generate a robust selection even if it doesn't result in substantial cost savings". This implies that CMS feels that it will have detailed information on what bidders in the first 10 competitively bid areas (CBAs) are willing to charge and, by implication, how low they can go and still stay in business. **CMS could and will use the data to impose an inherent-reasonableness standard on the entire industry. This will adversely affect rural providers nationwide.**

How will inherent reasonableness affect rural providers?

- The bidding process is effectively a closed auction subject to providers "gaming" the system.

• The rational view holds that individual bidders will logically adjust their bids to reflect their own company and market evaluation and expectations, but logic does not necessarily apply to the competitive bidding program - and this fact muddles the strategies of even the savviest HME bidding companies.

As we review the results of Round One we see that there were four different types of providers:

1. Speculative bidders who had no idea what their actual costs were and simply bid to win.
2. Indifferent bidders who bid with the intent to sell their business. These bidders bid below their cost with the idea or hope that the median bid would pull up their bid - but again bid only to win without consideration of the impact on pricing.
3. Bidders were concerned for their businesses and beneficiaries and had looked at their true costs, bid a realistic figure and lost the bid.
4. Bidders who similarly were concerned for their businesses and beneficiaries and bid, but fell under the pivotal bid and "won" the "winners curse". They bid a realistic figure but the median bid pulled them below what they can effectively afford to stay in business. They were forced then to accept a bid offer that they know will put them out of business.

A review of Round One proves this point:

(CMS reported this information to staff who attended an April 22 CMS briefing for congressional staff.)

- 6,358 bids were submitted.
- 1,005 separate and unique bidding numbers or an average of six bids per company. (Note: Due to several network-bidding entities, the number of unique bidding companies is estimated at 1,100 – 1,200.)
- 630 bidding entities were disqualified from the process due to various reasons; the majority for missing information from the applications. These bids were never considered within the pricing methodology. Of these, 283 were within the range "to win".
- 318 bidders were offered contracts.
- 316 returned a signed contract.
- Only about 5% of the eligible small providers were offered a contract, and about 16% of large providers.
- A total of 1,254 contracts were accepted.

Why were CMS' estimates in the Final Rule on competitive bidding so overstated? Does it really matter that 64% of the suppliers who were offered contracts were small suppliers when the total number of contracts offered (1,335) was only 14 % of what CMS had originally forecast they would offer in the Final Rule (9,584)? In the Final Rule CMS estimated that 60% of the bids would be awarded contracts. CMS received over 6,000 separate bids and only 1,335 were offered contracts (22.5%). What happened? Because of this failed system are rural providers now told they will

need to budget for a 26% cut based on the implementation of the inherent reasonableness provision? CMS has not shared bidding data or the criteria that they used to establish new Medicare payment rates or the criteria by which suppliers were evaluated. I question how CMS made their decisions on providers' financial viability and business expertise and am concerned that the inefficient manner in which the program was implemented threatens the integrity of the entire program.

Impact of DMEPOS Competitive Bidding on Beneficiaries

Eliminate Patient Choice:
Competitive bidding will simply limit choice for beneficiaries.

Currently Medicare beneficiaries have their choice of equipment suppliers. They base this choice upon the quality of service and the quality and appropriateness of the equipment provided to them. By its very nature, competitive bidding will significantly reduce the number of suppliers available to serve the beneficiary. Although proposals for national competitive bidding call for the establishment of quality standards, beneficiaries prefer the ability to choose from a wide range of providers to ensure quality, just as they do among physicians. Relying on government-defined and government-enforced standards is no substitute for the ability to move to another provider. That is why more than twenty organizations in the Consortium for Citizens with Disabilities Health Task Force have urged Congress to oppose national competitive bidding.

Reduced Service:
Competitive bidding will limit access to high quality, medically necessary products and services. When price becomes the primary determining factor for eligibility to serve Medicare beneficiaries, suppliers are under tremendous pressures to submit low bids by reducing or eliminating high quality product lines or more intensive beneficiary services. Medicare is the dominant purchaser of these goods and services, and few companies can survive without the ability to serve Medicare beneficiaries. Although the proposal contends that standards can protect quality, the government's ability to develop and enforce standards is untested. Further, standards are not a substitute for choice.

Curtailed Innovation:
Competitive bidding will stifle medical innovation.

Suppliers will be unwilling to base their bids on new medical technology and services, which often cost more than standard equipment and services but are more effective and have a greater positive impact on quality of life. If providers select lower cost items, this will have a rippling effect throughout the marketplace. Consequently, manufacturers will have no incentive to develop new technologies that improve outcomes or quality of life if the technologies raise up-front costs.

Threat to Small Businesses:
Competitive Bidding will eliminate small businesses.

The competitive bidding process awards contracts only to those suppliers that are able to offer a qualifying price. Consequently, many businesses will be excluded from the marketplace. Further, those small businesses that do win awards will face great difficulty in conducting business at reduced reimbursement rates and competing with large companies that have economies of scale. Indeed, in Polk County (one of the competitive bidding program demonstration sites from 1999-2001) after only two rounds of bidding, one national company emerged as the dominant provider in the Medicare oxygen market. The national company did not bid but acquired companies who won bids.

Monopoly / Expanded Government:
Competitive bidding will create a huge national bureaucracy at CMS and probably provide little savings. The National Business Services, Inc. (NBS) released a study that shows that the national competitive bidding program includes fifty separate legislative mandates or directives. According to NBS, the mandates will increase the CMS bureaucracy by over sixteen hundred personnel, or over one-third of its current size. In addition, a review of the Congressional Budget Office's (CBO) budget estimates for the national competitive bidding program by PricewaterhouseCoopers indicates that savings may not be substantial. Indeed, there is great uncertainty in the CBO's projections of $7.7 billion in savings over 10 years. According to PricewaterhouseCoopers reasonable assumptions, the entire program would save only a billion dollars over the same ten-year period.

Impact Competitive Bidding Will Have on the Beneficiary and the Transfer of Ownership of Oxygen Cylinders

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.

It is **neither safe nor fair to shift the burden of cost for maintenance and repair for medical equipment to disabled or elderly Medicare beneficiaries.** If the equipment is purchased, the patient incurs additional fees for clinical or emergency support or for exchange of malfunctioning equipment.

Oxygen is a Prescription Drug: Unregulated Use Poses Dangers and Burdens for Seniors

Medical oxygen can only be prescribed by a physician specifically for individual patient use. Oxygen is a drug and can be dangerous if not administered or used properly.

The use of medical oxygen equipment is imperative to the overall well-being of patients on oxygen therapy. Homecare companies currently provide 24-hour, emergency on-call service to assist patients with trouble-shooting equipment problems, improper use, or equipment failures.
The new rent-to-purchase payment policy for home oxygen equipment enacted in the Deficit Reduction Act (DRA) requires that after a 36-month rental period, title and responsibility for maintenance and service for all home oxygen stationary and portable technologies would be transferred to the Medicare beneficiary. The President's proposed 2007 budget would worsen the policy by forcing transfer of ownership and responsibility after 13 months.

With the transfer of ownership of the medical device to the patient, the control over the dosage levels shifts to the patient increasing the risk of self-medication to the patient's own detriment. This is an unreasonable burden and worry for seniors, especially on top of navigating Part D drug benefits. Just last week, one of my respiratory therapists was in a Salvation Army Store in Cedar Rapids, IA, and sitting there was an oxygen concentrator and three oxygen cylinders for sale - no doctor order required. As already stated, oxygen is a drug that must be prescribed by a physician, and when beneficiaries start owning this equipment, where will it go when they no longer need it? Obviously, for sale at a Salvation Army, maybe a local garage sale, the Internet...as a respiratory therapist this worries me to no end. Oxygen, when used inappropriately and without proper training, has very dangerous consequences that could result in death from underdosing or overdosing, or a deadly fire due to lack of training of the safe use and storage of oxygen. Providers currently educate each patient and their caregivers on these very critical issues.

Costs Related to Home Oxygen Therapy
Like many other medical therapies performed in conjunction with medical devices, the equipment cost is only a small fraction of the overall cost associated with the provision of home oxygen therapy.

What else do providers do?

- Provide 24-hour support for our patients. (This means I pay an employee to be on call after hours, weekends and holidays, and pay overtime and mileage when they do get called for a service call.)

- If a patient is having a problem, day or night, we help them troubleshoot the problem over the phone. If that is unsuccessful, we go to their home. We have traveled 90 miles round-trip to help a patient screw on a water bottle humidifier to their oxygen machine because they couldn't get the threads lined up correctly due to their arthritis, and no other caregiver was available.

- We brave the Iowa winters of snow and ice to get oxygen cylinders to clients due to an extended power failure, as their oxygen machine requires electricity to operate. The back-up oxygen cylinder system I place in every home of an oxygen user, at no charge to them or Medicare, lasted the patient 14 hours, but the power was out for several days.

• We provide professional respiratory therapists and nurses to visit our oxygen patients every 1-3 months to ensure the equipment is working properly and that they are using their oxygen as prescribed by their physician. We give them new supplies and change their tubing, we check their heart rate, blood pressure, oxygen level, listen to their lungs - all to determine their current condition. Any alarming findings are reported to their physician so that appropriate interventions can be made to prevent a hospitalization.

• We deliver tanks to our patient's home or meet them at the office on a Sunday morning because they want to go to church, and they forgot to call us and tell us their tanks were empty last Wednesday.

This is the short list, but I will stop here. Who is going to do all of this when patients own their equipment? I cannot provide these services for free, and not many of my fixed-income Medicare patients can afford to pay me extra out of their social security check for these services. So it will simply not get done. Patients will be hospitalized more often, and the Medicare program is going to see a rise in hospital expenditures much greater than the decline in the DME expenditures.

While there is broad language in DRA regarding "payments for oxygen" (the oxygen itself) and "maintenance and service" after the title transfer of the equipment, there are no specifics or assurances regarding availability of 24-hour emergency service and other services, supplies, and emergency back up required by home oxygen patients suffering from respiratory diseases such as COPD. In the Medicare system today there are no codes or policies governing the maintenance and services for oxygen technologies. The DRA provides no guidance for the myriad service components currently required and incorporated into the Medicare oxygen rules and payment, including all patient training, deliveries, disposable accessories, billing, clinical professional support, 24-hour emergency service and equipment replacement.

Nearly One Million Medicare Beneficiaries Receive Oxygen Therapy

Oxygen equipment is critical to approximately one million Medicare beneficiaries who suffer from respiratory illnesses such as chronic obstructive pulmonary disease (COPD) and who require oxygen therapy for their long-term survival. Approximately 15 million Americans have been diagnosed with COPD. An estimated 15 million more have undiagnosed COPD.

Home Oxygen Therapy is both Clinically Effective and Cost-Effective

Oxygen is the only current treatment or drug scientifically proven to extend the life of patients with chronic lung disease.

In 2002, there were 673,000 hospitalizations for COPD. Their average length of stay was 5.2 days. The average Medicare cost for one day in the hospital is $3,606, and the average admission for COPD therefore costs more than $18,000.

In contrast, the current average annual cost for home oxygen therapy is $2,784, less than the average cost for one day in the hospital. Home oxygen therapy is the most cost-effective and clinically effective treatment for those with COPD and low blood oxygen.

Conclusion

What does this mean to Palmer Home Medical Supply, rural hometown HME providers, and all other providers in a competitive bid area throughout America? I live in an area of the country with a large elderly population, and 43% of my clients are on Medicare. I truly fear what will happen to my customers and my small business when the competitive bidding storm thunders its way into rural America. I cannot survive if I can't serve Medicare beneficiaries, nor can I survive providing our current quality of product and level of service with a 26% cut in payment. Due to this competitive bidding storm, small businesses will be destroyed, and beneficiaries will be left to fend for themselves, threatening their current access to care and their quality of life.

I call on Congress to immediately delay the implementation of the competitive bidding program. As with any action that is taken to avert the train wreck that is competitive bidding, I ask that Congress include a repeal of the imposition of a 36-month cap on Medicare payments for home oxygen therapy. As a provider, I support the implementation of a rational alternative process to determine Medicare pricing for DME items and services.

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

1050 17th Street Northwest, Suite 600 Washington, DC 20036, 202-776-0652

National Coalition for Assistive and Rehab Technology

Written Testimony for the Record

Hearing on

"CMS competitive bidding demonstration for DME – Bad Medicine for Small Business."

In the

Rural and Urban Entrepreneurship Subcommittee

Committee on Small Business

of the

U.S. House of Representatives

May 21, 2008

On behalf of The National Coalition for Assistive and Rehab Technology (NCART), I appreciate the opportunity to testify regarding the impact of competitive bidding on small businesses and more specifically those involved in the provision of complex rehab technology. NCART is a coalition of suppliers and manufacturers of assistive and rehab technology products and services. The coalition's mission is to ensure proper and appropriate access to rehab and assistive technology for individuals with disabilities. CMS currently classifies rehab and assistive technology under the durable medical equipment (DME) benefit within Medicare.

Background

In order to understand how competitive bidding will impact small businesses in this industry, it is important to have a basic knowledge of these businesses. More than 50% of the providers in this

industry qualify as small businesses with annual revenues between $3 and $5Million. Most are privately owned businesses which are generally well entrenched in their communities and have established relationships with their customers and allied health professionals. Complex rehab and assistive technologies are adaptive seating, positioning and mobility devices that are evaluated, fitted, configured, adapted, and modified based on the unique clinical and functional needs of people with severe disabilities. These disabilities may include neurological or myopathic conditions, congenital deformities, and other complex and progressive diseases such as muscular dystrophy, ALS (Lou Gehrig's disease), spina bifida, cerebral palsy and spinal cord injuries. What differentiates complex rehab companies from other home medical equipment suppliers is the level of products that are supplied, the level of staff required to provide it and the amount of time and labor involved.

Companies that adhere to the long-standing service/delivery model that provides the best clinical outcome for consumers or complex rehab are required to employ certified staff and to run their operations in a certain way. All of this comes with a high cost. In a study performed by a D.C. based economics firm for NCART, companies operating in this field experience a net operating income of 1.6%[1]. This is based on non product costs in the 50.5% range along with a product cost of 47.9% for these companies. With such high non-product expenses and such minimal net operating income, the complex rehab technology industry is already unstable. Coupled with the cash flow challenges of dealing with third party payers and increases in things like fuel and payroll cost, these companies are even more challenged to remain viable.

It is also important to note that suppliers and manufacturers of complex rehab technologies have already absorbed significant cuts in reimbursement resulting from coding changes and congressionally mandated reimbursement cuts. Moreover, the CPI increase for the Medicare fee schedule for existing HCPCS codes has been frozen for almost a decade while costs associated

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[1] The Impact of Proposed Reimbursement Changes on Providers of Rehab and Assistive Technology: Evidence from a Provider Survey November, 2006 THE MORAN COMPANY

with the provision of this technology has increased. The DME industry in general has only received one permanent Medicare fee schedule increase since 1998.

Competitive Bidding Impact on Small Rehab Suppliers

Round one of competitive bidding continues to move forward in spite of many inequities and controversies that have been uncovered. The areas of concern range from both the resulting prices and their calculations to the actual winning bidders and how they were selected. CMS continues to claim that it has addressed all concerns appropriately but the fact still remains that many small businesses have already been injured by this program. The fact still remains that the single payment amounts for complex rehab were, to a great extent, based on bids submitted by companies with no experience in the provision of complex rehab, companies that have no experience providing any products within the specific CBA, and in several situations, bids submitted only in an effort to "practice" in preparation of round 2. The result is that the single payment amounts established for many complex rehab HCPCS codes are unrealistic.

Medicare is not the only payer for complex rehab technology but is often reported to account for about 30% of revenue for the typical rehab focused company. For a business with $1.5 million in revenue a Medicare portion of 30% would mean that $450,000 of their revenue was resulting from Medicare reimbursement. Using the costs reported in the Moran study, the impact of accepting a 15% reduction off the Medicare fee schedule in order to provide product in the competitive bidding areas would dramatically undermine the viability and long-term stability of the company as shown below.

RTC with Revenue of 1.5M Prior to competitive bidding	Cost of goods 47.9%= $718,500	Non-product related costs 50.5% = $757,500	Net Operating Income = $24,000
Post competitive bidding winner with 15% reduction in reimbursement for Medicare Sales (30% of total revenue) $1.4325M- a loss of revenue of $67,500.	Cost of goods would not change as a result of the cut in reimbursement	Non-product related costs would not change as a result of the cut in reimbursement $757,500	-$43,500 loss

	$718,500		
Post competitive bidding supplier looses Medicare business -$1.050M revenue	$502,950	Non-product related costs would not change $757,500	-$210,450 loss

It is clear from the above examples that a small supplier whether a winner or loser in competitive bidding is unlikely to be able to sustain a reduction in reimbursement or a loss of Medicare revenues. Given that many state Medicaid programs and third party payers use Medicare fee schedules and policies as a baseline this will further reduce the revenue for these companies and will cause further losses.

Unqualified companies awarded contracts in the CBAs

One obvious anomaly of round one is that the competitive bidding program is allowing suppliers with no physical presence in a Competitive Bidding Area (CBA) to enter a new market with an unfair competitive advantage and markedly fewer competitors. The program allows suppliers with no physical location in a CBA, no direct employed staff in the CBA and with no financial investment in the CBA to enter a new market by way of a Medicare contract. It is important to note that this unfair advantage has a strong potential to reduce service or responsiveness for Medicare beneficiaries in the CBA. Many small local rehab companies with years of experience in the market may be excluded from the program due to their composite bid price combined with the claimed capacity of competing bidders. The companies with a financial investment in facilities, staff, and equipment needed to repair and service devices, along with other costs associated with appropriate service of complex rehab technology requires a higher level of reimbursement than a supplier that has no financial investment. The industry of complex rehab companies supports an efficient, yet adequate service/delivery model. The model that the competitive bidding program promotes is one that fails to protect access and fails to ensure Medicare beneficiaries the services they need for a positive clinical outcome.

Additionally, some companies bid on product categories in CBAs that they had no intention of going in to. I personally have knowledge of a provider who bid in a CBA as practice. This means that their price was included in the calculation although they were not a serious entry in the process.

Accreditation standards were not adequately implemented

Companies that have not traditionally operated in a given business sector were also allowed to be awarded contracts based on a loophole in the accreditation standards. One example is a large provider of standard mobility products that was awarded the "Complex Rehab mobility" contract in several of the 10 MSAs. The company was accredited as an HME company because that was the only set of standards that could be applied when they were surveyed. Even though rehab standards have since been developed and are now a current requirement for passing accreditation, this company was able to be awarded a bid because their accreditation does not expire until 2009. This means that they were not required to meet the "rehab standards" in winning the bid. This is a company that has not historically been a complex rehab provider and has not employed complex rehab staff but they were able to bid and win against qualified small businesses that were already in the markets.

Small businesses may be forced to enter sub-contracts or networks to maintain their revenue

While CMS will allow suppliers to join networks or subcontract in order to maintain their ability to service a market, they will be forced to give up a greater piece of the reimbursement to participate. If a small business that is already struggling is forced to pay a percentage to the contractor who already bid a low price then the net effect will be even more devastating to these companies. If we use the above Moran assumptions and the average reimbursement reduction is already 15%, there is no more margin room for the sub-contracting supplier to give to the contractor in order to maintain the market.

In effect, round one has created no winners when it comes to small businesses or even large businesses. The bid prices have resulted from a flawed process and small businesses will be forced to pay the price if this continues to move forward. Allowing prices to be implemented that

are established out of fear, speculation or misinformation is irresponsible and will not serve the needs of Medicare's most disabled beneficiaries.

NCART strongly believes that competitive bidding will not work for complex rehab items and that ultimately it will cause an access issue for Medicare beneficiaries with disabilities. The large numbers of small businesses in our industry will begin losing money and will be forced to reduce staff or ultimately close their doors. This will force Medicare beneficiaries to abandon relationships with providers that they know and are comfortable with based on price and not a true ability to serve their needs.

It is critical that steps be taken to exempt complex rehab technology from competitive bidding and to preserve access to this important technology. The small businesses in this sector will need the assistance of Congress in order to make this happen. Legislation to exempt complex rehab from the national competitive bidding program has been introduced in both the House and the Senate. HR 2231 currently has 42 cosponsors in the House of Representatives. We urge this subcommittee to support HR 2231 and to actively seek to have this legislation enacted this year..

We appreciate the opportunity to testify in this hearing. Please direct any questions or concerns to NCART's executive director, Sharon Hildebrandt at 202-776-0652.

Statement of the
Quality Diabetes Care Coalition

Submitted to the
U.S. House of Representatives
Committee on Small Business
Subcommittee on Urban and Rural Entrepreneurship

May 21, 2008

The Quality Diabetes Care Coalition (QDCC) is grateful to the subcommittee for holding a hearing on the DMEPOS Competitive Acquisition Program and welcomes the opportunity to present this statement. QDCC educates policy makers and the public about the importance of home delivery supplies for Medicare patients with diabetes. Our goal is to ensure that these patients continue to have access to needed diabetes control products. The Quality Diabetes Care Coalition (QDCC) includes AOM Healthcare Solutions, an Owens & Minor Company, CCS Medical, and Liberty, a Medco Health Company.

Together, the members of our coalition provide diabetes testing supplies by home delivery to more than 101,000 Medicare beneficiaries who live in the 10 MSAs affected by round 1 of the DMEPOS Competitive Acquisition Program (*see attached chart*). That represents more than 70 percent of the estimated 143,000 Medicare beneficiaries in the affected MSAs that now have diabetes testing supplies delivered to their homes. As of July 1, thousands of these Medicare patients living with diabetes may be forced to switch from a trusted provider to some new source.

We are concerned about what will happen to our patients and about whether they will lose access to the high quality, trusted products and services they use every day when CMS forces them to switch providers less than six weeks from today. We are troubled that CMS bidding rules adequately ensure patient access to quality diabetes products. Nor has CMS taken appropriate steps to assure that winning bidders have the capacity necessary to provide these products or accompanying services that help beneficiaries monitor their conditions to avoid exacerbations and costly hospitalizations.

A well-intended Medicare bidding process designed to save money for the program could have the unintended consequence of disrupting care for patients living with this chronic condition. QDCC is urging a delay of implementation of this program until CMS can ensure that the rules are fair to all bidders and every Medicare patient living with diabetes will have full access to the products and services that they need to maintain their health.

Background

Nearly one in four Medicare patients suffers from diabetes, the sixth leading cause of death among American adults. Thousands of Medicare patients currently rely upon home delivery for their diabetes supplies, such as test strips and meters. Home delivery can mean better diabetes management. The convenience, especially to older patients, results in fewer interruptions to ongoing, regular testing, fewer trips to a pharmacy, and more patient privacy.

Because diabetes patients who have their supplies delivered to their homes are more likely to use them regularly, home delivery offers many advantages:

- Studies show that Medicare beneficiaries who are compliant incur 20-30% lower overall costs for healthcare than those who do not actively comply with regular blood glucose testing.

- Research shows that people with diabetes who perform fewer blood glucose tests than guidelines recommend have more hospitalizations and visits to the doctor than those who test more frequently.

- Home delivery bolsters ongoing patient compliance monitoring with education about the importance of complying with a prescribed testing schedule and regular delivery of diabetes testing supplies.

Home delivery, and the educational services these companies provide, is more than a mere convenience for these patients; it is an essential part of maintaining their health.

Problems with Round One of the DMEPOS Competitive Acquisition Program

Tens of thousands of beneficiaries may lose many or all of these benefits on July 1 when CMS implements competitive bidding for DMEPOS in the 10 MSAs. We believe that the bidding process contain several flaws that must be corrected prior to implementation. To be clear, QDCC is not requesting a repeal of the Medicare competitive bidding program. Rather, we are calling on CMS to rebid the first round using rules that will ensure parity among bidders and guarantee seniors access to quality diabetes products.

Specifically, we believe that the following flaws in Round 1 of competitive bidding need to be corrected:

- **Patient access to quality products was not adequately protected.** Thousands of Medicare patients in the affected markets may have to change where they get their home-delivery diabetes testing supplies. It is not clear who their new suppliers will be or whether they will provide the same product choice or service quality as do the current suppliers. The competitive bidding process did not guarantee access to products and services currently recommended by physicians. Physicians, seniors and Medicare patients must have confidence that contracted suppliers have the ability to provide disease control products to all who depend on them.

- **CMS did not adequately ensure that contracted suppliers have the financial soundness or the capacity to provide quality products to a growing number of Medicare diabetes patients.** Every 21 seconds, another person is diagnosed with diabetes – that's more than 1.5 million new diabetics each year. As this program begins, it's essential it be built well in order to accommodate new patients. Unfortunately, it is not clear if contracted suppliers have the financial soundness or capacity to provide needed products to the almost 10 million patients who already rely on these convenient, trusted diabetes management products.

- **CMS did not put the DMEPOS Competitive Acquisition Program on a proven path to savings.** Unlike all the other DMEPOS product categories, in the diabetes supply category, CMS chose to exempt retail pharmacies from prices set for competitive bidding. As a result, unless suppliers that won bids to deliver products to the home provide the same or equivalent products or services as are provided today, patients may turn to physical retail stores for their supplies. In such cases, Medicare will realize no savings. Worse yet, because disease management compliance is lower when patients buy their supplies from retail outlets than when they are delivered to the home, these patients are more likely to suffer complications, including more hospitalizations.

QDCC Recommendations

In order to correct these problems, QDCC is calling for CMS to delay implementation of the first round and rebid contracts according rules that would:

- **Provide more specific formulary requirements.** In the new request for bids, CMS should be specific about its needs and the parameters for diabetes supplies. There are multiple products of varying quality in this product category and bidders need direction. Potential bidders should be required to offer and inventory a specified level of product, such as at least two of the top four leading brand products based on national volume statistics. All suppliers, regardless of size, should offer a minimum level of product choice. Suppliers should not be allowed to offer less choice based on size or experience in the market.

- **Ensure uniform reimbursement.** All channels of distribution should be included and treated equally in the competitive bidding program. Medicare should ensure uniform reimbursement regardless of whether the products are delivered to the home or purchased at a retail outlet.

- **Ensure capacity and financial soundness.** CMS should establish standards that guarantee supplier capacity through objective and transparent standards. CMS should rely on a supplier's historical Medicare volume or clear measures of financial soundness to determine capability. Bids won in other MSAs should be taken into account when evaluating bidders' financial information. CMS should look at a supplier's bids won in other MSAs and in other product areas in determining a company's financial soundness and capacity.

- **Ensure that bids are legitimate.** In order to preserve the integrity of the system, CMS should require all bid contracts to be binding if a bidder is selected as a winner. Entities that bid at or below the single payment amount should not be permitted to decline to supply products so long as the terms of their contract with CMS are not materially different from the submission.

- **Strengthen program integrity and compliance.** Winning bidders should meet program integrity requirements that further strengthen ethical compliance, as specified by the HHS Office of Inspector General (OIG) in its compliance guidance to Durable Medical Equipment Suppliers. The final rules for the competitive bidding program held that suppliers disclose information regarding revocations of supplier numbers, sanctions, program-related convictions, exclusions, or debarments. However, to further strengthen ethical compliance, CMS should require that all suppliers include an existing "program integrity" system as part of its operational infrastructure. This should include, at minimum, a compliance officer, a compliance plan, and regular audits of key areas (sales, claims, document integrity).

We again thank the Committee for allowing us to set forth our recommendations and look forward to working with Congress and the Administration in ensuring that seniors retain access to high quality products and services in the Medicare program.

May 21, 2008

The Honorable Heath Shuler
Chairman
Small Business Subcommittee on Rural and Urban Entrepreneurship
US House of Representatives
Washington, DC 20515

The Honorable Jeff Fortenberry
Ranking Member
Small Business Subcommittee on Rural and Urban Entrepreneurship
US House of Representatives
Washington, DC 20515

RE: Preserving Appropriate Access to Assistive Devices Under the Medicare DMEPOS Competitive Bidding Program

Dear Chairman Shuler and Ranking Member Fortenberry:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition write to request your assistance in ensuring that the Medicare competitive bidding program does not decrease access to and the quality of assistive devices. The ITEM Coalition is a consumer-led coalition of disability-related organizations with the goal of improving access to assistive devices, technologies and related services for individuals with disabilities of all ages.

We are suggesting a series of proposals that we believe will relieve some of the potential access problems that are likely to occur when competitive bidding is implemented on July 1, 2008. These proposals include exempting certain devices and technologies which are uniquely fit to the individual from being competitively bid, allowing beneficiaries with complex technology needs to opt-out of the competitive bidding program and continue to access their current supplier, and requiring Medicare to establish a dedicated community ombudsperson and a toll-free number to assist and track beneficiaries that are negatively impacted by competitive bidding.

Competitive Bidding and Quality Issues

The competitive bidding program for Durable Medical Equipment, Orthotics, Prosthetics and Supplies ("DMEPOS") was enacted as part of the Medicare Modernization Act of 2003 ("MMA"), and CMS is currently in the process of implementing the first round of the program. CMS has recently announced an acceleration of implementation of Round 2 of the program. The Administration estimates that the program will save Medicare approximately $1 billion annually once fully implemented. ITEM Coalition members, however, are concerned that a portion of that savings will result from beneficiaries not receiving the most appropriate device to meet their medical needs.

Often individuals with spinal cord injuries, multiple sclerosis, cerebral palsy, amyotrophic lateral sclerosis ("ALS"), and other severe disabilities require assistive devices that must be fitted and/or programmed to

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meet their individual needs. In addition, technology assessments and home evaluations are often performed in order to ensure that the appropriate equipment is provided.

The first round of the DMEPOS competitive bidding program would significantly cut reimbursement for the 10 targeted product categories. In fact, CMS estimates that on average, the price Medicare will pay suppliers is 26% lower than current payment rates. As a result of this dramatic price reduction, we suspect that suppliers will have difficulty purchasing, servicing, and providing the same quality devices and associated services to consumers. The likely decrease in the quality of assistive devices and technologies, especially complex devices and technologies which are highly individualized and fitted, threatens the consumer's function and independence. Additionally, the use of improper equipment could result in related medical complications (e.g. bed sores, shoulder injuries) for the individual. 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.

While we support efforts to appropriately reduce the copayments paid by Medicare beneficiaries and the costs of assistive devices and technologies paid by Medicare, we cannot support a system where quality is compromised as a result. To do so would be to undervalue the importance of appropriate assistive devices and technologies to the health and independence of individuals with disabilities and chronic conditions.

Competitive Bidding and Access to Suppliers

Another primary concern of ITEM Coalition members is that individuals requiring assistive devices and technologies will face supplier access problems as a result of the significant decrease in the number of suppliers available to them.

We understand that in the bidding process, suppliers 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, and CMS has used those estimates to determine who has been offered competitive bidding contracts. CMS apparently conducted no independent verification of these supplier estimates. ITEM Coalition members are very concerned that the huge decrease in the number of suppliers in MSAs and the arbitrary way in which CMS has determined the number of suppliers necessary in each MSA will result in serious access problems on day-one of the competitive bidding program.

Additionally, the process in which CMS has determined the number of suppliers in an area denies many beneficiaries the opportunity to continue long-standing relationships with their current supplier. Imagine that you are a complex power wheelchair user who has gone to the same supplier, located just four blocks from your home, for over 20 years. This supplier has detailed knowledge of your disability and related conditions and, as a result, has a history of providing you with the most appropriate wheelchair to meet your needs. However, because this supplier was not selected as a contractor in the Medicare competitive bidding program, as of July 1st, you will have to start all over with a new supplier who has no historical knowledge of your particular disability and related needs, does not carry your specific brand of wheelchair, and is located more than five miles from your home. For consumers with long-term needs who heavily depend on their current suppliers for appropriate devices, evaluations, and consistent services, the competitive bidding program simply does not make sense.

ITEM Coalition Requests for Members of Congress

Given the serious concerns expressed above, ITEM Coalition members offer the following proposals for how Congress and CMS can work to help ensure that individuals with significant disabilities are not harmed by the DMEPOS competitive bidding program. We are proposing two potential options to accomplish this goal. The first option, a general carve-out for complex devices, is a *benefit-focused* proposal, while the second, an opt-out provision, is a *beneficiary-centered* proposal.

> **1) The ITEM Coalition requests that Congress and CMS exempt from competitive bidding complex devices and technologies which must be uniquely "fitted" to the individual user.** These complex items, such as Group 3 power wheelchairs, are provided to individuals with the most severe disabilities and often require very individualized programming, fittings, and evaluations. Such complex technology has no place in a competitive bidding program with a general, one-size-fits-all reimbursement structure. Congressman Allen (D-ME) has introduced The Medicare Access to Complex Rehabilitation and Assistive Technology Act (HR 2231). This legislation would 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. ITEM Coalition members support enactment of this legislation.
>
> **2) The ITEM Coalition would like to work with Congress and CMS to craft a way in which beneficiaries with long-term needs who require complex assistive devices and technologies may chose to opt-out of competitive bidding and keep their current DMEPOS supplier in order to ensure continued quality of care and choice of supplier.** Under this option, consumers with long-term or complex needs could choose to continue accessing their supplier of choice at the Medicare DMEPOS fee schedule amount, an option that would amount to "grandfathering" in the Medicare parlance. 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 supplier. This opt-out provision would be most useful in the first year of the program when continuity problems are most likely to arise.

The ITEM Coalition also requests that Medicare be required to establish a separate toll-free number specifically for beneficiaries regarding competitive bidding questions and concerns. CMS should also assign an ombudsperson to help monitor and resolve access and quality concerns. Currently, Medicare is instructing individuals with competitive bidding concerns to call 1-800-Medicare. Unfortunately, this is the general number for Medicare-related questions and, as a result, consumers often face long waits and operators who may not be knowledgeable in the specific area in which they have questions.

We suspect that leading up to and following the implementation of the competitive bidding program, consumers will have numerous and important questions regarding the changes in the DMEPOS benefit. We feel that a specific toll-free number for such questions staffed by individuals knowledgeable in the new competitive bidding program, as well as access to an ombudsperson, is an important safeguard in implementation of this program.

Additionally, the ombudsperson and toll-free number could prove to be a vital tool in monitoring the first round of the competitive bidding program. *The information gathered could then be used to assess whether or not CMS should move forward with implementation of the second round or whether a delay should occur to allow CMS and stakeholders appropriate time to study and address any and all access problems that arise.*

Conclusion

The Medicare DMEPOS competitive bidding program is a massive experiment set to impact one of the nation's most vulnerable populations – individuals with disabilities and chronic conditions. Yet, despite a lack of knowledge of the program's impact, CMS is moving forward with its implementation at an accelerated pace.

The ITEM Coalition is extremely concerned that competitive bidding will significantly threaten access to and quality of assistive devices, technologies and related services that are vital to the health and independence of consumers. We hope that Congress will work with CMS to implement appropriate safe guards to insure that individuals with disabilities are not harmed or overly burdened by the upcoming changes. And it is vitally important that the concerns of consumers are addressed as quickly as possible given that we are now merely two months away from the first round of the programs' implementation.

We thank you for your continued attention to the health and independence of people with disabilities and chronic conditions. We look forward to working with you to ensure that the Medicare DMEPOS competitive bidding program does not harm the vulnerable population which this benefit was designed to serve. Please contact the ITEM Coalition at (202) 349-4260 with any questions.

Thank you for your consideration,

American Academy of Physical Medicine and Rehabilitation

American Association of People with Disabilities

American Foundation for the Blind

American Medical Rehabilitation Providers Association

American Music Therapy Association

American Occupational Therapy Association

American Physical Therapy Association

Brain Injury Association of America

Center for Medicare Advocacy, Inc.

Easter Seals

Hearing Loss Association of America

Long Island Center For Independent Living, Inc.

Medicare Rights Center

National Association of Councils on Developmental Disabilities

National Council on Independent Living

National Family Caregivers Association

National Multiple Sclerosis Society

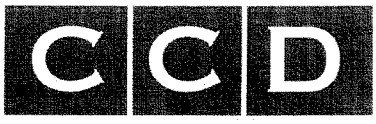
Paralyzed Veterans of America

Rehabilitation Engineering and Assistive Technology Society of North America

The Arc of the United States

United Cerebral Palsy

United Spinal Association



CONSORTIUM FOR CITIZENS WITH DISABILITIES

May 21, 2008

The Honorable Heath Shuler
Chairman
Small Business Subcommittee on Rural and Urban Entrepreneurship
US House of Representatives
Washington, DC 20515

The Honorable Jeff Fortenberry
Ranking Member
Small Business Subcommittee on Rural and Urban Entrepreneurship
US House of Representatives
Washington, DC 20515

RE: Impact of DME Competitive Bidding on Medicare Beneficiaries with Disabilities and Chronic Conditions

Dear Chairman Shuler and Ranking Member Fortenberry:

The undersigned members of the Consortium for Citizens with Disabilities (CCD) are writing to state our concerns with the pending Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding program and its impact on beneficiaries with disabilities and chronic conditions. We have several specific requests to protect consumers which include a delay in the implementation of the program, specific protections and options for individuals with the most significant disabilities, and administrative safeguards if and when the program is implemented.

The CCD is a coalition of national disability-related organizations working together to advocate for national public policy that ensures the self determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society.

Many CCD members have opposed the DMEPOS competitive bidding program since the negotiations on the Medicare Modernization Act of 2003 ("MMA"). 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.

If beneficiaries are not concerned about provider choice and would prefer to lower their copayments, they have a simple solution available to them: they can join a Medicare Advantage

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plan. But if they choose to remain in the fee-for-service program, their choice of supplier should not be restricted unless the supplier is not qualified to provide the benefit.

To be sure, CCD is not opposed to adjusting reimbursement levels for items and services under Medicare 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 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 consumers with disabilities and chronic conditions will pay in the form of access, quality and choice.

Consumer Concerns With Competitive Bidding for DMEPOS

As CMS begins to implement phase I of the national DMEPOS Competitive Bidding program, we are hearing from our members and numerous other stakeholders regarding the potential threats to access and quality of assistive devices and technologies under this program. As a result, we have objectively analyzed the program and have listed our primary concerns below.

1.) ***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. The 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 improper 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.

2.) ***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 and home evaluations are often 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 be 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.

3.) ***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. This limitation in access to the provider of choice means a great deal to people who have developed close personal and clinical relationships with their DMEPOS suppliers. CCD is very concerned that the huge decrease in the number of suppliers in the MSAs and the unverified manner in which CMS has determined the number of suppliers necessary in each MSA will result in serious access problems.

Additionally, 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.

4.) ***Impact on Consumer-Supplier Relationships***: Many Medicare beneficiaries may wake up on July 1st to find that they can no longer purchase items from their supplier who they have worked with for many years, has detailed knowledge of their disability and related conditions, and a history of providing them with the most appropriate devices to meet their needs. These long-standing consumer-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.

5.) ***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.

Policy Recommendations to Congress

Congress strategically enacted the competitive program to be phased-in over a several- year period by 2010. Unfortunately, because CMS fell behind in the implementation of the first round, to now be implemented in 10 MSAs on July 1st, the agency has accelerated the implementation of the second round, to be implemented in 70 MSAs next year, in order to meet the 2010 deadline. Because of this accelerated timeline and the consequential lack of data on the impact of the program on consumers, time is of the essence for Congress to act to protect beneficiaries.
CCD is making the following requests to Congress in order to protect consumers with disabilities:

1.) ***Delay implementation of the first round of 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.***

2.) ***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 people with disabilities and chronic conditions.***

3.) ***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 (HR 2231), 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.

4.) ***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 co-payment 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.

5.) ***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.

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.

We thank you for your consideration and look forward to working with you on this important issue. Please contact the Peter Thomas (202-466-6550), Liz Savage (202-783-2229), or Kathy McGinley (202-408-9514) with any questions.

Sincerely,

American Association of People with Disabilities
American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Occupational Therapy Association
America Physical Therapy Association
Association of Assistive Technology Act Programs
Association of University Centers on Disabilities
Brain Injury Association of America
Disability Rights Education and Defense Fund
Easter Seals
Independence Care System
Lutheran Services in America
National Association of Social Workers
National Disability Rights Network
National Multiple Sclerosis Society
National Rehabilitation Association
National Spinal Cord Injury Association
Paralyzed Veterans of America
The Arc of the United States
United Cerebral Palsy
United Spinal Association

THE ORTHOTIC AND
PROSTHETIC ALLIANCE

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Washington, DC 20005
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STATEMENT FOR THE WRITTEN RECORD

SUBMITTED BY

THE ORTHOTIC AND PROSTHETIC ALLIANCE

TO THE

HOUSE COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP

Hearing on Competitive Bidding for Durable Medical Equipment

May 21, 2008

American Academy of Orthotists and Prosthetists (AAOP)
American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC)
American Orthotic & Prosthetic Association (AOPA)
National Association for the Advancement of Orthotics and Prosthetics (NAAOP)

Chairman Shuler, Ranking Member Fortenberry, and Members of the Subcommittee:

This statement is being submitted for the written record by the Orthotic and Prosthetic Alliance ("O&P Alliance"). The O&P Alliance is a coalition of four of the primary organizations representing the field of orthotics (orthopedic braces) and prosthetics (artificial limbs). The four organizations include the American Academy of Orthotists and Prosthetists ("AAOP"), the National Association for the Advancement of Orthotics and Prosthetics ("NAAOP"), the American Orthotic & Prosthetic Association ("AOPA"), and the American Board for Certification in Orthotics, Prosthetics, and Pedorthics ("ABC"). The O&P Alliance represents the professional, scientific, research, business, and quality improvement aspects within the fields of orthotics and prosthetics.

The O&P Alliance welcomes the opportunity to comment on CMS regulations and programs that impact small providers of health care services. Other than one national company, the field of orthotics and prosthetics ("O&P") is predominated by small businesses. Specifically, the O&P Alliance submits these comments on the competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") provided under the Medicare program.

It is important to understand, however, that when Congress enacted competitive bidding, it specifically decided to not apply competitive bidding to all prosthetics and the vast majority of orthotics. In fact, even though Congress has provided in statute that competitive bidding could be utilized for off-the-shelf orthotics only, CMS has declined to include O&P services in either of the first rounds of competitive bidding in recognition of the unique, individualized nature of O&P care. So, as of today, O&P is not a participant in the CMS competitive bidding initiative, and O&P patients would be best served if things remain that way. There are important reasons for exempting O&P care from competitive bidding, which this testimony details. We believe this exemption is good news for the 1.8 million amputees and millions of people with musculoskeletal impairments who are in need of prosthetic and orthotic care in this country, many of whom are covered by the Medicare program.

I. Medicare Competitive Bidding has the Potential to Harm Patients

The O&P Alliance opposes competitive bidding on principal because we believe it will negatively impact patient choice of supplier, quality and access to care. Competitive bidding of DMEPOS disproportionately impacts and unfairly places at risk Medicare beneficiaries with musculoskeletal and other disabilities. 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.

Patient choice of provider/supplier in the Medicare Part B program is an important quality assurance mechanism, as any beneficiary can simply choose another qualified supplier if their current provider is not meeting their needs. The current fee schedule makes price a constant and ensures that suppliers compete for Medicare beneficiaries by providing excellent service,

meeting patients' needs, and 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 become secondary factors.

II. All Prosthetic and Orthotic Care Should Be Permanently Exempt from Medicare Competitive Bidding

Prosthetics and custom-fabricated orthotics are excluded from the competitive bidding program by statute. Congress exempted all prosthetics and most orthotics from competitive bidding for several reasons, primarily because of the highly customized nature of O&P professional care. Inherent in the provision of O&P care is a high level of clinical service and professional judgment, unlike the provision of commodity-based durable medical equipment ("DME") and supplies.

As such, the level of education, skill, and experience necessary for practitioners to provide comprehensive O&P care differs dramatically from that required for the supply of DME and supplies. The competitive bidding statute—the Medicare Modernization Act of 2003—did give CMS some discretion to include very basic orthotics, a very small subset of the O&P field known as "off-the-shelf" orthotics, into the competitive bidding program, but CMS determined that off-the-shelf orthotics would not be included in the first and second rounds of the competitive bidding program. Therefore, all O&P care is currently unaffected by Medicare competitive bidding.

The O&P profession is opposed to the inclusion of *any* orthotic or prosthetic items and services in the Medicare competitive bidding program. CMS conducted two demonstration projects on competitive bidding, one of which—conducted in San Antonio, Texas—included some basic orthotics. This demonstration project showed that while there were some cost-savings in utilizing competitive bidding for off-the-shelf orthoses, the relatively small amount of money saved by the government did not justify the expense of administering a competitive bidding program for these orthoses.

Further, competitive bidding is not an effective means of delivering the services that fall under the umbrella of prosthetics and orthotics. All prostheses and most orthoses are custom designed to address the specific anatomical and functional needs of each patient. The provision of O&P care requires varying degrees of clinical intervention and expertise in order to properly fit the patient. Even off-the-shelf orthoses cannot always be safely and appropriately utilized by the patient, and the professional judgment of the clinician is still needed to determine the level of care needed by the patient.

The relationship the patient forms with the O&P clinician is similar to that of a patient's relationship with his or her physician. It is for these reasons that Congress chose not to apply competitive bidding to all prosthetics and nearly all orthotics. O&P professional care is simply not a commodity and in no way lends itself to competitive bidding. "Low-ball" bidders would likely not possess the professional judgment necessary to make assessments about the

complexity of O&P care needed by the patient. Providing O&P professional care through the lowest bidder is counter to the way quality orthotic and prosthetic care is best delivered.

In addition, quality of care would suffer as practitioners would be forced to search for ways to cut costs so they could remain financially viable. It would not take long before suppliers would have no choice but to discontinue product lines that are no longer sufficiently profitable or that require extra time or attention to the beneficiary. This would be to the detriment of patient outcomes. Competitive bidding would eventually impede medical innovation. Suppliers with Medicare contracts at low rates of reimbursement would be reluctant to adopt new technologies that improve clinical outcomes but may be more expensive for the supplier to purchase from manufacturers. Simply put, competitive bidding would reward those suppliers who would provide the least expensive O&P componentry, employ minimally qualified staff, and utilize the least expensive O&P techniques and materials, essentially creating a "lowest common denominator" care system.

The O&P Alliance also believes that access to care would be adversely affected by competitive bidding. If Medicare were to competitively bid orthotics and prosthetics, fewer available patient care facilities would necessitate more travel for the patient. Orthoses and prostheses are typically fit to persons with a disability or orthopedic impairment. Requiring these patients to travel further, especially as they frequently require aid with transportation, would place additional burdens on patients and families. Moreover, there are occasions when beneficiaries will require off-the-shelf and more complex O&P care at the same time. In this scenario, the beneficiary may be required to travel to two different facilities to receive needed services.

We do not support Medicare DMEPOS competitive bidding on principal, and strongly oppose its application to orthotic and prosthetic care. We do so because competitive bidding takes the emphasis off of providing quality patient care and achieving patient satisfaction and focuses on price alone. We continue to have serious concerns with the impact that DMEPOS competitive bidding will have on the quality of care and supplier choice available to Medicare beneficiaries under the Part B program.

III. Budget Neutral Alternatives to Competitive Bidding

Recently, proposals have surfaced that acknowledge the widespread concerns with DMEPOS competitive bidding, especially the manner in which CMS has implemented the program. This very hearing is an indication that as the implementation date of July 1st for the first round of competitive bidding nears, concerns among all stakeholders are intensifying. We are aware of informal legislative proposals to eliminate DMEPOS competitive bidding and, in its place, impose a budget neutral fee schedule adjustment. The O&P Alliance believes that 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.

In addition, if Medicare fee schedules are to be adjusted downward in order to offset the costs of eliminating competitive bidding, the O&P Alliance believes that such

adjustments must be confined to the range of DME items and supplies currently subject to competitive bidding in rounds 1 and 2 (as opposed to over-extending the "pay-for" to all who *potentially could have been subject* to competitive bidding under the statute). This would be far more equitable than an across-the-board fee schedule adjustment *all* DMEPOS fee schedules. For instance, because all prosthetics and virtually all orthotics are exempt from competitive bidding by statute, the O&P fee schedule should not be included in any offset proposals to compensate for the repeal of competitive bidding for DME and supplies included in rounds one and two of the program.

Thank you for this opportunity to submit our statement for the record. If we can be of further assistance, please contact Peter W. Thomas, Esq. at (202) 466-6550.

The Power Mobility Coalition

WORKING TOGETHER FOR FREEDOM AND INDEPENDENCE

May 28, 2008

The Honorable Heath Shuler, Chair
The Honorable Jeff Fortenberry, Ranking Member
House Small Business Subcommittee on Rural and Urban Entrepreneurship
U.S. House of Representatives
2361 Rayburn House Office Building
Washington, DC 20515

RE: Hearing on Medicare DMEPOS Competitive Bidding Program

Dear Chairman Shuler and Ranking Member Fortenberry:

The Power Mobility Coalition (PMC), a nationwide association of suppliers and manufacturers of motorized wheelchairs and power operated vehicles, applauds the House Small Business Subcommittee on Rural and Urban Entrepreneurship 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.

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[1] *See*, Testimony of Mr. Thomas Ryan, former chairman of the American Association for Homecare, before the Subcommittee on Health, Committee of Ways and Means at p. 2 (May 6, 2008).

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 182,000 PMDs were provided by Medicare or 26% (61,000 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.

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[2] *See*, CMS-10116 Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles (CMS-3017-IFC) (April 27, 2007).

- **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 information 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.

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[3] *See*, 42 U.S.C. § 1847(b)(10).

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 recent hearing on DMEPOS competitive bidding before the House Ways and Means Subcommittee on Health, the GAO testified that CMS needs to closely monitor competitive bidding, through beneficiary and supplier surveys and other oversight, to ensure access and that contracted supplier's meet capacity.[4] 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.

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[4] *See*, Statement of Kathleen King, Director, Health Care, General Accountability Office before the Subcommitee on Health, Committee on Ways and Means at p. 3 (May 6, 2008).

- **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 to delay competitive bidding or, in the alternative, on developing 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

May 28, 2008

The Honorable Heath Shuler
Chairman, Rural and Urban Entrepreneurship Subcommittee
Small Business Committee
U.S. House of Representatives
512 Cannon House Office Building
Washington, D.C. 20515

Dear Chairman Shuler:

Thank you for holding the Rural and Urban Entrepreneurship Subcommittee hearing on May 21 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.

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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

DMEPOS State Licensure Requirements

As part of the Medicare DMEPOS supplier standards, a supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.

Standard #1 of the Medicare DMEPOS Supplier Standards states: "*A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements*."

To receive and retain a Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) supplier number, suppliers must be in compliance with this standard.

This link provides a directory of state licensure requirements on the various DMEPOS items: http://www.palmettogba.com/palmetto/statelicensure.nsf.

This directory is a guide of the types of licenses required by the state. Licensure requirements vary from state to state and locality to locality, so suppliers must check with the state and local governments for the most current licenses required. Examples of licenses and permits required are sales permits, state sales tax, professional licenses for various fields (e.g., respiratory, orthotics, prosthetics), pharmacy licenses, oxygen licenses and DME licenses.

Statement of:

National Association of Chain Drug Stores

On:

Competitive Bidding for Durable Medical Equipment

To:

U.S. House of Representatives
Committee on Small Business
Subcommittee on Urban and Rural Entrepreneurship

May 28, 2008

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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,

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[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.

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 that any proposal to cut and/or freeze the DME fee schedule would 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 CMS 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-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

[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.

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 initial 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.

[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).

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 with 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 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.

Monitoring and review of beneficiary experiences and quality of products and services is critical.

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 critical in advance of implementing further rounds of the program.

CMS should involve pharmacists and other providers in drafting patient communication materials.

With only five weeks remaining before first round mail-order diabetic supplies contracts go into effect in the 10 MSAs, CMS has yet to embark upon an effective 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 from 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.

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