SUBCOMMITTEE HEARING ON COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT: WILL SMALL SUPPLIERS BE ABLE TO COMPETE?

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SUBCOMMITTEE HEARING ON COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT: WILL SMALL SUPPLIERS BE ABLE TO COMPETE?

Wednesday, October 31, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT
Washington, D.C.

The Subcommittee met, pursuant to call, at 2:00 p.m., in Room 2360, Rayburn House Office Building, Hon. Jason Altmire [chairman of the Subcommittee] Presiding.

Present: Representatives Altmire, González, and Gohmert.

OPENING STATEMENT OF CHAIRMAN ALTMIRE

ChairmanALTMIRE. This hearing on ″Competitive Bidding for Durable Medical Equipment: Will Small Businesses Be Able to Compete?″ is now called to order.

As more baby boomers age into Medicare, few would disagree that reform is necessary. But change presents unique challenges for the program, its beneficiaries and the medical providers that support it. That is why changes to Medicare must be made carefully and with a great deal of thought and input.

Today's hearing will shed light on the importance of small durable and medical equipment suppliers to the Medicare program. It will allow the Subcommittee to fully understand the implications of the project that affects both small health care providers and patients' access to care. Small firms are an essential part of Medicare and fill gaps larger businesses either cannot or will not fill.

On April 2, the Centers for Medicare and Medicaid Services issued its final rule on competitive bidding for durable medical equipment. The program allows Medicare to award contracts for durable medical equipment to suppliers with the lowest bids. CMS maintains that the program will not only ensure beneficiary access to quality medical supplies and services, but will also reduce beneficiary out-of-pocket expenses and improve the effectiveness of payments. But the question remains, what will competitive bidding mean to the small business community? And do its benefits outweigh the costs?

CMS has estimated that within 5 years of implementing the program, the savings to taxpayers will exceed over $1 billion annually. The potential for gain cannot be ignored, but these reforms could have enormous ramifications on small businesses. While the objec-

tive is to reduce costs, it is not clear that the new competitive bidding program will achieve this goal without unraveling the DME small business community.

Small suppliers make up well over 90 percent of the Nation's medical equipment providers. To its credit, CMS appears to acknowledge the value of small firms to the DME marketplace, and the program pays deference to this importance by putting in place rules that protect certain categories of small suppliers. It also encourages the formation of small supplier networks in its final rule.

But these actions provide little relief to many small suppliers. By CMS's own estimation, once the competitive bidding program has taken full effect, as little as 20 suppliers on average will be initial bid winners in each area. Even with small business protections in place, few small firms can expect to be actual bid winners. This may spell ruin for small business providers whose revenues are often less than $1 million per year.

What seems clear about CMS's competitive bidding program is that the only businesses certain to survive the agency's payment reform will be the national suppliers. Small businesses may be the backbone of this country, but the manner in which the competitive bidding program is structured may challenge their very survival.

The issue is of particular concern to me because western Pennsylvania is one of the first 10 areas to implement competitive bidding. I worry that CMS has not considered the unintended consequences that may result from the program, including the possibility that patients may lose the personal relationship they have developed with their local provider, in turn compromising their quality of care.

Further, I have concerns that western Pennsylvania will be disproportionately impacted by competitive bidding and that it may force some local small businesses to close their doors and working families may lose their jobs. Congress must take a long look at the competitive bidding and impact that it will have on small suppliers.

Though there is little doubt that Medicare must be reformed, in my view small businesses should not shoulder that burden. The panelists here today are well equipped to talk about reasonable ways to ensure this does not occur.

I look forward to today's testimony, and I thank all of our witnesses for their participation. I now yield to Mr. Gohmert for his opening statement.

OPENING STATEMENT OF MR. GOHMERT

Mr.GOHMERT. Thank you, Chairman. And good afternoon to everyone. And thank all of you for being here as we examine the Centers for Medicare and Medicaid Services' competitive bidding program for certain durable medical equipment, prosthetics, orthotics and supplies. Boy, that is a mouthful, isn't it?

And I would like to say, Chairman, I really appreciate your having the hearing, and I appreciate your emphasis. I think you and I are of the same heart on this issue. But on December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement Modernization Act of 2003. This legislation produced the largest overhaul of Medicare in the public health's 38-year history. Among other things, the legislation required CMS to use com-

petitive acquisition procedures when entering into contracts for durable medical equipment, prosthetics, orthotics and supplies under Medicare Part B. A single payment amount for each item derived under the new competitive acquisition project through competitive bidding will replace the current payment amounts.

The new competitive acquisition project is the subject of today's fact-finding hearing to acquire a better understanding of the CMS competitive acquisition project definition and impact on small business medical suppliers. In developing the competitive acquisition project procedures relating to competitive bidding and the awarding of contracts, this CMS is required by legislation to take appropriate steps to ensure the small business medical suppliers have an opportunity to be considered for participation. Because as we know, small business provides 70 percent of the jobs in the United States, legislation here does not require the demonstration be subject to Federal acquisition regulation.

For our part, 19 implements Federal Government policy, provides maximum practicable opportunities in its acquisitions to small business, veteran-owned small business, service disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned business concerns. Such concerns must also add the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency consistent with efficient contract performance.

Competition is the foundation of capitalism. Competition stimulates innovation, encourages efficiency, drives down prices, saving taxpayer dollars. Small business has historically been the engine of innovation and a catalyst for competition. They also, as I say, they have most—70 percent of all new jobs provided.

While I support competition and the outcomes it normally produces, I want to ensure that the competitive acquisition project's design and methodology meets the intent of the Small Business Act by supplying small business medical suppliers the maximum practical opportunities to participate in the competition as both prime contractors and subcontractors.

Additionally, it is imperative that we look at the big picture and make sure that folks who need these services are getting the best quality care they can. I think that is something that is oftentimes overlooked in Congress. We should not only get overly caught up only in the numbers but look to how the rules and regulations affect the folks back home in our districts.

We have excellent witnesses here today to provide us with insight in the rationale behind the competitive acquisition project's definition of small business medical suppliers, and how the project's competition methodology ensures maximum practical opportunities for them. I look forward to their testimony. And thank you, Mr. Chairman, and yield back the balance of my time.

ChairmanALTMIRE. Thank you, Mr. Gohmert. I see that we have been joined by Congressman González. Did you have a statement?

Mr.GONZÁLEZ. No.

ChairmanALTMIRE. Let me just say in starting, it is probable at some point during this hearing we are going to be called for a vote. And what we will do at that point is temporarily recess the hear-

ing. We will walk over to vote. We will come back and we will pick up where we left off.

We have two panels today. The first one is Laurence Wilson. And I know that you have testified before, but for the benefit of all of our panelists, the way the light system works that you have in front of you is when you see the green light, that means you have 5 minutes from the time that light goes on. When that light turns yellow, you have one minute remaining. So please start to wrap up. And then when it turns red, your 5 minutes is up. So please summarize your remarks, and end your testimony at that time.

So our first witness today in our first panel is Mr. Laurence Wilson. He is currently the Director of the Chronic Care Policy Group in the CMS Center for Medicare Management, where he has responsibility for Medicare policy on a broad range of fee-for-service health care benefits, including post-acute care, home health, durable medical equipment, dialysis and various hospital services. He is also responsible for administering the agency's process for the coding of drugs, devices and other items and services. Mr. Wilson has worked at CMS since 1988.

Welcome, Mr. Wilson. We look forward to your testimony.

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

Mr.WILSON. Good afternoon, Chairman Altmire and distinguished members of the Committee. I am pleased to be here today on behalf of the Centers for Medicare and Medicaid Services to discuss the durable medical equipment prosthetics, orthotics and supplies competitive bidding program mandated by the Medicare Modernization Act of 2003.

This initiative will reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare's payments, help combat fraud and ensure beneficiary access to high-quality items and services. Each year suppliers provide critical items and services, such as power wheelchairs and oxygen equipment to address the care needs of over 10 million beneficiaries.

Over the past decade, Medicare expenditures have more than doubled from approximately $5 billion in 1997 for this benefit to over $10 billion annually. Fraud and abuse has been a significant concern in this area of Medicare program with numerous instances documented by the Office of Inspector General, General Accounting Office and other law enforcement agencies. Broadened abuse has no doubt contributed to this dramatic growth in this area of Medicare.

The three charts that I have provided in the written testimony and to my right provide examples of the dramatic growth and expenditures for certain items. Power wheelchairs, negative pressure wound therapy and oxygen. For example, this first chart shows the growth in Medicare expenditures for power wheelchairs from 1995 to 2006. During this period, total allowed charges grew from $59 million to $980 million, over or over 1,500 percent. More accurate prices under Medicare will reduce incentives to commit fraud by making it less lucrative, while overall, resulting in more appropriate level of expenditures for durable medical equipment. Lower

prices will also provide value to beneficiaries who will now pay less in coinsurance.

The Office of Inspector General issued a report yesterday showing that on average Medicare fee schedule amounts or current payments in the area of power wheelchairs were 45 percent higher than median Internet retail prices available to consumers in 2007. This study, along with the examples for other products included in CMS's written testimony, shows the potential value that could result from our competitive prices.

In addition, the application of quality standards under this program by independent accreditation organizations as well as application of financial standards will help ensure that patients receive quality items and good customer service and that Medicare contracts with viable suppliers will be there for the long term to meet patients' care needs.

In developing this program, CMS worked closely with suppliers, manufacturers, and beneficiaries through a transparent public process. This included public meetings and forums, the existence of an external advisory board. In addition, beneficiary and small business focus groups were convened in several cities across the country to bring special focus to their concerns. As a result, CMS's policies and implementation plan pay close attention to the needs of beneficiaries and small suppliers.

I would note that CMS very much appreciates the detailed comments from this Committee, which were very helpful in the formulation of our final regulation. In that rule, CMS adopted numerous approaches to ensure small suppliers have the opportunity to be considered for participation in the program.

First, consistent with the recommendation of the Committee, CMS worked with the Small Business Administration to develop a more representative definition of a small supplier in contrast to the more general definition of a small business. CMS then designed specific policies linked to this new definition to help small suppliers.

For example, the final regulation allows small suppliers to band together networks in order to meet the requirement to serve an entire competitive bidding area. The regulation also employs a formula to ensure that multiple suppliers will be selected for each of the 10 product categories in an area. In this way, the largest suppliers will be unable to dominate the bidding process. All winning suppliers will continue to compete based on quality and customer service, and each supplier's share of the market will ultimately depend on patient choice.

Most importantly, the regulation establishes 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 will add small suppliers to the list of winners to reach this target.

The first round of competitive bidding is currently underway. Over 6,300 certified bids have been submitted by interested suppliers in the 10 metropolitan areas. We are very pleased with this result, and we are evaluating the bids currently. We recognize that some suppliers experience difficulty, and we are working on

changes to the system to alleviate those concerns with a view towards round two when we will expand the bidding to 70 MSAs.

In summary, the new competitive bidding program will bring value to Medicare and its beneficiaries. More accurate prices along with accreditation and financial standards will result in improved quality and customer service for patients and form an important part of the agency's overall effort to eliminate fraudulent suppliers in Medicare and protect America's seniors.

I thank the Committee for inviting me here today, and I am pleased to answer any questions the chairman or other Members may have. Thank you.

[The prepared statement of Mr. Wilson may be found in the Appendix on page 115.]

ChairmanALTMIRE. Thank you, Mr. Wilson. The bidding process ended on September 25 after the need for multiple extensions to allow bidders to submit those bids. Whenever CMS proposes to start the program in an MSA, whether it be the first phase of 10 MSAs or the second phase of 90 MSAs or even nationwide, will you start with a new bidding process in each MSA?

Mr.WILSON. We will, as we did in round one in 10 MSAs, publish a request for bid. We will indicate a timeline for suppliers to submit their bids and commence education for suppliers so that they can meet all the specific requirements associated with the bidding process and move forward much in the same way.

We do have some changes that we plan for round two. In particular, I mentioned in my testimony an improved bidding system, online electronic bidding system. We recognized suppliers had problems there. We are going to fix that, make it better for suppliers, and we will move forward, giving suppliers additional information they need.

ChairmanALTMIRE. Is it CMS's position that each MSA is different, has unique circumstances surrounding each one and therefore should have a different bidding process, separate bidding process?

Mr.WILSON. They do indeed have a separate bidding process. And we certainly agree that each MSA is different. They are geographically different. Some have—like Riverside, California, has some very low population density areas in the west—or in the eastern part of that county that borders Nevada. We excluded those because it didn't make sense for beneficiaries or suppliers to have to cover that type of territory. So we will consider those types of unique circumstances when we go forward with the bidding process.

ChairmanALTMIRE. Thanks. Now it is my understanding that CMS limited eligibility initially to small businesses with $3.5 million in annual revenue, but the SBA's limit is $6 million in annual revenue. So could you please explain the rationale behind this inconsistency in the application of small businesses?

Mr.WILSON. What we wanted to do in this area of the program was try to target small suppliers, truly small suppliers. The small business definition was fairly general and included almost—and I think one of the—Mr. Gohmert pointed this out—90 percent of the suppliers that we have participating in Medicare. We wanted to

find out who were a subset of that and make sure that they would participate because we wanted to ensure that not just large suppliers would have an opportunity to participate but the ones that were truly small had special policies to help them out. And that is why we changed that definition.

ChairmanALTMIRE. Okay.

Mr.WILSON. And I would point out that the specific definition was recommended by small suppliers who commented on the rule.

ChairmanALTMIRE. Thank you. I just want to get something clarified with you here. Based on the final rule for the competitive bidding program, the rule leaves unanswered the question of whether DME suppliers will be able to withdraw from offering to supply an item if it is below their submitted bid price. So just for the record, can you clarify CMS's position on this issue?

Mr.WILSON. Yes, sir. I certainly can. Suppliers will submit a bid. They may fall in the winning range. They may not fall in the winning range. We will let them know. We will provide them an answer to their bid, whether it is accepted or not. If it is accepted, they will have to sign a contract with us. They don't have to sign that contract. So they can decide if they don't like the price that we are offering and turn it down. Just because they submit a bid, we won't force them to participate.

ChairmanALTMIRE. Thank you. And my last question for this first panel, then we will turn it over to the ranking member. In 2003, the Medicare Modernization Act added dentists, podiatrists, and optometrists to the definition of physicians who may contract with Medicare. Given this shift in policy, why has CMS chosen not to extend the limited exception to the DME competitive bidding requirements to podiatrists, dentists, and optometrists?

Mr.WILSON. We did receive a number of comments from podiatrists. They asked us to include podiatry in the definition of the statute, and it is my understanding that we did do that. Now I think there was some additional concerns expressed by podiatry with respect to other exceptions we granted physicians and whether they were—whether the items that they supplied would be included there. We didn't do that at this point, but we haven't yet included those items in competitive bidding either.

I would like to go back and provide you a written answer to that because I want to make sure that I am correct in what I am telling you with respect to what we did in the final rule.

ChairmanALTMIRE. Okay. That will be fine. We will confirm through a letter.

Mr.WILSON. Thank you.

ChairmanALTMIRE. Thank you. I will turn it over to the ranking member, Mr. Gohmert.

Mr.GOHMERT. Thank you, chairman. The difference in 2,200 of the suppliers that actually applied and the 15,000 that were anticipated still concerns me. But let me ask you what steps that seem—that the Centers for Medicare and Medicaid had incorporated into the accreditation process to minimize cost and resource impact on small medical suppliers. What input did you actually have from them?

Mr.WILSON. We had quite a bit of input, sir. We had focus groups with suppliers. In particular, we discussed the quality standards.

They had concerns about the quality standards and accreditation, not with respect to the fee necessarily that was charged by accreditation organizations but with the cost of coming into compliance with the standards.

Mr.GOHMERT. I guess a better question would be—and you mentioned the focus groups and all. I guess I should have gone straight to not how many did you hear from, but how much attention did you actually pay? I mean, we have got Members of Congress that they go home all the time, listen to their constituents and then come up here and do something completely different. But back home, they think they are listening because they do. But then they don't put that into application. So how did you go about incorporating in the application process what they said, what you heard?

Mr.WILSON. Well, I think we did a great deal. Let me just start with a pretty simple metric from my standpoint. What we proposed was 114—I am sorry—about 120 pages in requirements for the quality standards. The final document was 14 pages and just focused on the core standards. A lot of standards that they were concerned about that went to record keeping and documentation requirements, whether or not they had posted business hours versus we had an original requirement that said 40 hours of office hours they had to keep. We got rid of that and just said posted business hours.

So we listened to a lot of different, very specific issues and eliminated a lot of requirements that were of particular concern to small businesses, and I would be happy to send you a list of some of those.

Mr.GOHMERT. Okay. Well, let me also ask, the competitive bidding rule permits physical and occupational therapists to provide off-the-shelf orthotics without participating in the bidding process, but physicians are not allowed to do that. And you know, obviously physicians play an important role in the treatment process. So I am curious why physical therapists were carved out but not physicians.

Mr.WILSON. Well—

Mr.GOHMERT. You figure they make enough money as it is? I am just curious.

Mr.WILSON. Not the physicians that I talk to, but the—I guess what I would say was we did establish a limited exception for physicians that allowed them to really—we allowed them to remove themselves from competitive bidding as long as they were serving a specific core set of items to only their patients. So we did provide that physician exception to provide certain things to just their patients. They couldn't act more broadly as a supplier in the community, but to the extent that they were treating their patients and their patient needed a walker, for example, to leave the office, we allowed them to do that without having to go through competitive bidding.

Does that answer your question, sir?

Mr.GOHMERT. Yes. Somewhat. Apparently you provided a limited carve-out for physicians. Is that the same extent to which physical or occupational therapists are allowed their carve-out?

Mr.WILSON. I believe it is somewhat different.

Mr.GOHMERT. Yeah. It sounds more restrictive.

Mr.WILSON. It is more restrictive in those other areas, and—

Mr.GOHMERT. So the physical therapists would know more than the doctors would about what was needed, is that where we are going here?

Mr.WILSON. Where we are going is that we only carved out a very, very limited set of items and services from competitive bidding provided by those practitioners.

Mr.GOHMERT. And I understand there is always a balance there. I have always had concerns about, you know, if you allow a physician to prescribe medications and then fill those prescriptions, then obviously there could arise a conflict. But let me move on.

It is my understanding that you didn't include diabetes testing supplies sold at retail in the competitive bidding demonstration projects and also excluded diabetes supplies sold at retail from first round of competitive bidding. So what is CMS's intention for the second round with respect to ensuring patient access to diabetes testing supplies?

Mr.WILSON. Well, one of the reasons that we excluded from competitive bidding diabetes supplies sold at the retail pharmacy outlets or store fronts was because a lot of concerns were raised with respect to access and with respect to patients getting the information they might need from pharmacists and others with respect to how those glucose monitors or test strips or items would be used and how to interpret the results. So we did carve that out. Now with respect to round two, we have not yet announced the items that will, or product categories that will fall under round two or the areas. We are considering that now and expect to provide the answer that you need within the next couple of months.

Mr.GOHMERT. So you don't have an answer yet?

Mr.WILSON. I do not.

Mr.GOHMERT. Well, looks like we may need another hearing. Thank you.

ChairmanALTMIRE. Mr. González.

Mr.GONZÁLEZ. Thank you very much, Mr. Chairman. And welcome, Director Wilson. I want to start off by what I generally start off with, and that is the observation that this Committee kind of looks at things a little differently than most other Committees. You may have testified before other Committees, Ways and Means or Energy and Commerce, but we are more oriented about the impact of Federal policy on small businesses.

The United States Government is the biggest purchaser of services and products than anyone else, any other entity in the world. So what we attempt to do is to make sure that small businesses are part of that whole equation, and we even tried to institute through policy and orders and even legislation that they somehow get to participate in this contracting. The biggest problem that we have had in the past with government services and products—and any small businessman or woman out there, they are going to love the word—it is bundling. The question that comes to my mind, do we have here the mother of all bundling? And that is going to be a real concern.

I am not saying that you are the cause of this. I think we have given you a very difficult, difficult mission, and that is attempting

to save as much money as possible, but it would appear—it is counterintuitive to us because you start off with the proposition of probably limiting the number of businesses that will be eligible to contract with the Federal Government for reimbursement for their service or their product. I think that is what we are really here to look at today. And you may be able to reconcile some of that.

But I do want you—when I ask for your response after I finish this two-part question—to address that. Do you see that as a special challenge to you as you attempt to accomplish what the Medicare Modernization Act attempted to accomplish in mandating what you were doing?

The other part of my question goes to your demonstration projects. I am from San Antonio. I represent half the city. That was one of the sites. The other was in Florida. I still don't know that it is Polk County or Dade County.

Mr.WILSON. Polk.

Mr.GONZÁLEZ. But I was just wondering, the second part of my question really goes to what you may have learned from that experience as being valid when you apply it to what you are attempting to accomplish by areas that are huge compared to what I would think would have been San Antonio or Florida. And I am talking about the competitive bidding areas, the CBAs based with MSAs combination and so on. Can you really rely on what you believe you learned in your demonstration projects and apply it to such a huge or larger—not just geographical but obviously a population that you are going to have now when you actually roll out what we have here today with CBAs?

So the first question is, do you see any conflict here as going basically with the proposition that if you accomplish your goal, you probably have cut out small business? There may not be a role for small business in what CMS is attempting to do. And we have run into this problem with other agencies and departments in government. You wouldn't be alone. And then secondly, the lessons that you believe and the savings that you believe you accomplished under the demonstration projects, do they really translate into the bigger and the more real picture that you presently find yourselves in?

Mr.WILSON. Thank you, Congressman. With respect to the first question, I think we have done enough to ensure that small suppliers are included. I think the type of policies we put in, in particular a policy that requires us to add to the list of winners suppliers that meet our small supplier definition, will ensure that there will be small suppliers participating in this program. That is as close to a guarantee as you can get. I think at the end of the day there may be fewer suppliers operating in these areas because Medicare will now only be contracting with the ones that can offer the best value, ones that meet our quality requirements and ones that meet our quality and accreditation requirements and ones that meet our financial standards. But at the end of the day, I think we have done enough to ensure that they have a role and will be participating and there for the long term.

But again we do recognize that some may not be. Some may go into other lines of business, some may go and provide items and products to different payers other than Medicare. Some may pro-

vide other items that don't fall under competitive bidding. But I think there will be a role for these suppliers within this program based on the policies that we have created.

With respect to the second issue, I mean I think we learned a lot during the demonstrations. You know we have learned some of the big things, like you can achieve savings through this type of program. We certainly know the VA and other types of programs, even private payers do this type of competitive acquisition process and have been successful at it. So we know their savings. We looked at quality very closely, and we were able to see that quality was maintained, access was not hindered. So we think those types of things, those sort of big things can be achieved.

At the same time I think we learned a lot. We learned that suppliers need transparency, they need to understand the rules. This is complicated, and we need to help them. And I think that is something that we take very seriously as we move forward with the implementation of not just this current round but the upcoming round. I think it is achievable.

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

ChairmanALTMIRE. I wanted to ask one more question, and then I will offer the same opportunity to each of the Committee members that are here if they wish.

And that is, that trained and licensed medical practitioners are by and large knowledgeable and skilled in the use of DME for patient care. So why does CMS believe it is necessary for them to on top of that be accredited by a CMS-recognized organization?

Mr.WILSON. Well, that is a very good question and one that we have heard a lot about from different practitioner organizations. Certainly the statute does require that all participating suppliers be accredited. And so we considered this very carefully. We looked at our authority. We looked at the comments. And what we felt was at the end of the day the type of service, the type of delivery, the type of beneficiary education on these particular products was unique enough that we wanted to have a standard requirement for everybody, a level playing field for everybody so that we could ensure not just quality but that everybody participating in the program had to meet a common set of requirements.

ChairmanALTMIRE. Thank you. Mr. Ranking Member, do you have a question?

Mr.GOHMERT. Yeah. But let me go ahead and ask specifically, why do you think instead of the 15,000 projected suppliers applying that we had 2,200?

Mr.WILSON. 2,200 is not a number that CMS has used, sir. I am not sure where that came from.

Mr.GOHMERT. Okay. What number are you using?

Mr.WILSON. Well, the number that I shared with you today was that we received across the 10 product categories, across the 10 metropolitan areas, 6,300 certified bids submitted.

Mr.GOHMERT. Okay. So that is still less than half of what was expected, and those are from some pretty big areas.

Mr.WILSON. Well, I think that is right. I think there is some confusion about what is talked about in the final rule versus reality. What is talked about in the final rule is the number of supplier sites that may fall under the bidding, the total potential supplier

sites. In fact, when suppliers submit bids, suppliers under common ownership only submit one bid. So a big company—and I know a bunch of big companies bid as well as small suppliers—will submit one bid for 100 sites. So that is not factored into that number.

So it is somewhat confusing. You have to read the language carefully in the rule. But I think the numbers are much closer together than folks may have been thinking when they looked at that large number.

Mr.GOHMERT. Well, I am just concerned that it may be like the old story about ending on something in Chinese and saying, if you are a small business and you want to participate, you have to be able to read that. Can you read that? Yeah. It says, there are not going to be any small businesses participating. But I am hoping that won't be the case.

ChairmanALTMIRE. Mr. González?

Mr.GONZÁLEZ. I will be brief. Thank you, Mr. Chairman.

Director Wilson, you would agree though once we implement this plan, you will have fewer businesses eligible to conduct business in the supply of durable medical equipment?

Mr.WILSON. I agree that is likely. I also know that once we learn a lot from this program, you know, we can offer prices based on what we have learned in competitive bidding to other market areas and use those prices for everybody.

Mr.GONZÁLEZ. And I understand that. And there is a learning curve on all this. But in the meantime, the businesses go under.

The second part of the question is, because there will be fewer, less, whatever the appropriate term is, as far as choice, do you think that impacts the quality of care that will be available to patients, to beneficiaries as far as maybe picking the best product that is best suited for their condition? You will have less choice?

Mr.WILSON. I don't—I hope not. We have done a number of things to ensure that doesn't happen. At the end of the day, we have a program that provides greater value. Suppliers will now be accredited to meet quality standards and meet financial standards so that they are there for the life of the contract to meet patients' needs. So we will have a better, I think a better environment for providing that care, which will promote the quality.

We also have specific policies to promote quality, an anti-discrimination clause which says if you are a supplier and you provide this brand to your private pay patients, well, you have to relay that to Medicare. We have a transparency policy where we will publish and update the list quarterly all information on models and brands provided by suppliers as the statute directed us to. We will have a physician authorization policy that allows physicians to pick a particular brand and have that provided if the patient needs that for medical reasons.

So there are some protections in place for beneficiaries. Beneficiary protections and small supplier issues were the two key issues in this final rule. So we have tried to address those.

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

ChairmanALTMIRE. Mr. Wilson, thank you for being here today. If we could get some clarification in writing on the couple of issues that we brought up.

Mr.WILSON. Yes, sir.

ChairmanALTMIRE. You are excused. But if you could allow at least one of your staff to remain here for the remainder of the hearing in case we have questions, that would be appreciated.

Mr.WILSON. Thank you.

ChairmanALTMIRE. I call to the table the second panel. We will begin. We will introduce each witness individually and then they will have the opportunity to offer their testimony and then we will introduce the next witness. So in that order for all six of you.

We are going to have a vote called in approximately 10 to 15 minutes. So at that point we will hear the remainder of the testimony for whoever happens to be speaking. We will recess for probably 20 minutes to a half-hour and we will return to finish the hearing.

So at this point I want to introduce Dr. Ross Taubman. He is certified in foot and ankle surgery by the American Board of Podiatric Surgery and is the current President-Elect of the American Podiatric Medical Association, which is the Nation's leading podiatric organization, representing approximately 80 percent of the podiatrists in this country. Dr. Taubman's practice is located in Clarksville, Maryland, where he focuses on elective and reconstructive foot surgery and limb salvage for patients with diabetes. Welcome, Doctor, and we look forward to your testimony.

STATEMENT OF DR. ROSS TAUBMAN, PRESIDENT ELECT OF THE AMERICAN PODIATRIC MEDICAL ASSOCIATION, AMERICAN PODIATRIC MEDICAL ASSOCIATION

Dr.TAUBMAN. Thank you. Mr. Chairman Altmire, Ranking Member Gohmert and Mr. González, I welcome the opportunity to testify before you today on behalf of the American Podiatric Medical Association.

I am Dr. Ross Taubman, President-Elect of the APMA and a practicing doctor of podiatric medicine. We represent approximately 80 percent of the podiatrists in the country, and our members provide the majority of foot care services to the Medicare population.

Mr. Chairman, more than 60 percent of the podiatrists in this country practice in one or two-person groups and would be considered small businesses. We do not believe Congress intended to construct new barriers for small businesses in recent legislation, including the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, but the unintended consequences have been serious for podiatry practices.

PPMs have been defined as physicians within their scope of practice under Title 18 of the Social Security Act since 1967. One of the provisions of the MMA that authorizes the competitive acquisition program cites a restrictive definition of physician that includes only medical doctors and doctors of osteopathy but not doctors of podiatric medicine. This restrictive definition could prevent patients from obtaining necessary DME as part of their care from their podiatrists.

Because this exclusion of podiatrists appears in the law, CMS has stated that Congress must make a technical correction to the MMA to resolve this issue. APMA urges Congress to take such action this year as part of a broader Medicare package, ensuring that

podiatric physicians can continue providing DME to our elderly and disabled patients.

The competitive acquisition program presents specific challenges to small business medical practices. Physician suppliers dispense small amounts of DME as part of patient care. According to 2004 CMS data, physicians and other practitioners were responsible for only 3.1 percent of DME-allowed charges. It is unclear what, if any, program improvement would be realized by imposing these requirements on physician suppliers.

Consider this CAM walker used when treating foot or ankle fractures. If subject to competitive bidding, I would need to make a bid to Medicare and be selected as a winning bidder to be able to continue to supply these items to my patients at the point of care. This is a completely uneven playing field from a cost basis. Since I may stock only two or three of a given item at a time in my small office, there is no way I can take advantage of economies of scale compared to a large supply house that purchases thousands of these items at a time.

Mr. Chairman, not only would this be unfair to me as a small businessman, but more importantly, it is certainly not good medical care. We shouldn't be sending patients out of our offices to get these medically necessary products in acute care situations.

Therefore, I urge Congress to exempt all physician suppliers that dispense DME as part of their patient care from the competitive bidding process.

The Medicare program's new accreditation requirements for DME suppliers are time consuming, expensive and heavy on paperwork, precisely the type of barrier which poses special difficulties for small businesses.

Consider that podiatrists who supply DME receive an average of $7,000 per year from Medicare. Accreditation costs a minimum of $3,000 per office for up to a 3-year period. It is not difficult to understand why we find it impractical to seek accreditation.

Furthermore, this accreditation requirement is unnecessary for physicians, given the comprehensive medical education and stringent licensure process to which we are already subject. Applying the same accreditation standards to physicians that are applied to large-scale suppliers is unnecessary, unfair, anti-competitive and costly duplication of existing rigorous processes. Therefore, physicians should be exempt from this supplier accreditation requirement.

Another DME-related burden arose recently when CMS proposed to require all physician suppliers of DME to furnish CMS with a surety bond. Since podiatric physicians generate only an average of $7,000 per year in allowed annual charges, most are almost certain to stop providing DME products under Medicare if the surety bond requirement is implemented.

Congress recognized that including physicians in surety bond requirements was bad policy. The Balanced Budget Act of 1997 states that such surety bonds requirements should be applied to suppliers, quote, other than physicians or other practitioners, end quote. Moreover, the report language states unambiguously that, quote, the conferees wish to clarify that these surety bonds require-

ments do not apply to physicians and other health care professionals, end quote.

Given the clarity of that statutory report language, APMA does not understand why CMS proposed to include podiatrists and other physicians in the surety bond requirement.

In conclusion, implementing rules whose predictable outcome is the exclusion of thousands of small businesses from supplying DME to Medicare beneficiaries is bad for physician practices and the patients whom we serve. Podiatric physicians must be permitted to continue to prescribe and supply DME products. Additionally, physicians should be allowed to provide essential durable medical equipment as part of patient care without the burdens of competitive bidding, additional accreditation or posting of surety bonds.

Mr. Chairman and members of the Subcommittee, again thank you for providing me with the opportunity to speak today on behalf of the APMA. Attached to my written testimony are comments that we have submitted to CMS and other background documents. I respectfully submit these letters to the Subcommittee and ask that they be included in the record. I will be happy to answer any questions you may have.

[The prepared statement of Dr. Taubman may be found in the Appendix on page 37.]

ChairmanALTMIRE. Without objection, they will appear in the record.

We will go next to John Shirvinsky. He is the Executive Director of the Pennsylvania Association of Medical Suppliers, established in 1972. The Pennsylvania Association of Medical Suppliers is the oldest State association of its kind in the country dedicated to providers of home medical equipment and supplies and the patients they serve. Welcome, Mr. Shirvinsky.

STATEMENT OF JOHN SHIRVINSKY, EXECUTIVE DIRECTOR, PENNSYLVANIA ASSOCIATION OF MEDICAL SUPPLIERS

Mr.SHIRVINSKY. Thank you, Mr. Chairman, Mr. Gohmert.

First, PAMS would like to commend and thank this Committee for taking the opportunity to examine the impact of CMS's competitive bidding program for DME and for looking at the question, will small suppliers be able to compete? The question might as well be, will small suppliers be able to survive?

One small supplier in Pittsburgh who does about 65 percent of his business with Medicare recently told me that this is a question that literally keeps him up at night. You see, competitive bidding is an exclusionary process. It is one that produces winners and losers and, of necessity, it produces far more losers than it does winners. Since the vast majority of HME suppliers are small and independently owned, it should stand to reason that small independently owned companies will bear the brunt of the burden.

CMS did attempt to create some small provider-friendly provisions, such as small supplier networks for the purpose of submitting joint bids, but even that effort failed. To the best of my knowledge, no small providers were able to successfully form such a network in the Pittsburgh competitive bidding area. I am unaware of

any small supplier networks that were able to be formed anywhere in the country. I can only vouch for Pittsburgh, none were formed there.

Instead, what small providers in Pittsburgh did is they formed ad hoc subcontracting arrangements as a matter of survival. Each provider agreed that they would submit their own bids and secured letters of intent from one another to provide products and services throughout the CBA as subcontractors. Now that was a clever idea. But why should honest hard-working business people need to come up with clever ideas in order to survive in an otherwise healthy market?

Competitive bidding has been a bad idea from the git-go. It was inserted into the Medicare Modernization Act of 2003 in the middle of the night just prior to final passage. It was not properly vetted, it was not properly thought through. It makes pretensions about its ability to save money, again on a very, very small portion of Medicare spending, that are simply unsupportable and unsustainable. It makes no account for its impact on businesses, communities, employment, product quality, quality of care or the potential for increased hospitalizations that may result. It is a program that promotes the concentration of market share, yet takes no notice of the inherent dangers in such concentration.

The CMS competitive bidding process received failing grades from Pittsburgh-area providers of all types and sizes. From the many providers with whom I have spoken, it has been called flawed, ridiculous, unworkable, overwhelming, frustrating, crazy, uninformed, anti-private enterprise, absurd, disturbing and misdirected. I made up none of those, although I did clean up a few.

CMS has contended that DME competitive bidding represents a market-based efficiency. It is at best dubious to suggest that this program represents anything close to healthy market economics. Competitive bidding is a tool that can be used to great effect by government so long as it is carefully targeted and promotes competition. Think highway and facility construction or, you know, even office supplies or local trash collection. The DME competitive bidding process is none of these things. It is complex, far reaching and burdensome. It is a government-sponsored scheme to eliminate competition by dismantling a national network of HME providers that has reliably serviced the home health needs of Medicare patients for decades. Medicare beneficiaries, CMS, and this Congress will live to regret the day that this network of independent DME providers was dismantled as a result of this ill-considered program.

Medicare is the dominant insurer in the DME market. With this program, CMS is attempting to manipulate the market for purposes that will not result in meaningful savings, that will not ensure better service for people in need, that will result in layoffs, that will result in small business closings, and that will result in the loss of tax revenues to State and local governments.

The Medicare population is growing larger and older with each passing year. For the HME industry, that means a growing market. Under free market economic theory, that should mean that more competitors should be entering this market, helping to drive down or stabilize pricing in the face of increasing demand. It is inconceivable that it would be the U.S. Government that would come

forward with a scheme to concentrate market share and eliminate competition given such conditions.

What CMS is doing is a formula for certain higher prices down the road. Competitive bidding for DME is not good business. It is bad news. The most responsible thing that this Congress can do on this count is to admit that a previous Congress made an error in approving a poorly considered provision. I urge this Subcommittee to support the repeal of competitive bidding and to set this Nation's small and independently owned HME providers free to meet the needs of America's aging population.

I thank you for this opportunity to testify.

[The prepared statement of Mr. Shirvinsky may be found in the Appendix on page 79.]

ChairmanALTMIRE. Thank you, Mr. Shirvinsky. And at this time we will recess the hearing until 3:15.

[Recess.]

ChairmanALTMIRE. Thanks, everybody, for waiting. That should be our last interruption for this hearing.

We left off at Ms. Carol Gilligan. She is president and owner of Health Aid of Ohio. For 23 years her company has taken care of Cleveland's elderly and disabled.

Recognized nationally as one of the of the top three rehabilitation wheelchair companies for 3 years in a row, Health Aid has taken care of thousands of patients. They closely interact with patients at Metro Health, the Cleveland Clinic Melon Center, and the Children's Rehab, to name just a few

Just this month, Carol's company received the industry's reward as the number one rehabilitation provider in America.

Welcome Ms. Gilligan.

STATEMENT OF CAROL GILLIGAN, PRESIDENT, HEALTH AID OF OHIO, INC., CLEVELAND, OHIO

Ms.GILLIGAN. Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to talk to you today about the Medicare program and its implementation of competitive bid acquisition programs for durable medical equipment, prosthetics, orthotics and supplies, and its impact on my small business and the consumers I serve.

A copy of my written statement has been provided to you for the record. My name is Carol Gilligan, and I am President of Health Aid of Ohio in Cleveland, Ohio. I started my small business in 1984 to serve seniors and people with disabilities. My company primarily provides what we call complex rehab equipment and services to people with specialized needs.

I started my company, small business, over 20 years ago after meeting a girl in my neighborhood who has a rare form of muscular dystrophy. I brought her mold today because that small girl is 26 years old right now, and that is her shape of her body and her custom seating. So Emily is with us today.

My business was inspired by my desire to be able to really help people with special needs and mobility limitations. This year I was honored to be awarded the best rehab provider in the United States by HME News, an industry trade publication.

I would like to explain the types of services my company provides to consumers and how the bidding program will impact my program and consumers. Provision of complex rehab technology is not a commodity. Complex rehab and assisting technology consists of highly individualized products and services that are prescribed by a physician and provided to individuals by specially trained and credentialed members of the rehab technology profession.

It is different from traditional durable medical equipment products in that rehab products are evaluated, fitted, configured, adjusted or programmed to accommodate each individual's specific and unique medical needs, taking into consideration the individual's medical history, diagnosis, disease progression, functional needs, anatomical anomalies and requirements as well as the typical environments that individual encounters throughout the course of their daily activities.

I am accompanied today by my friend David T. Williams of Ohio, and I invite you and members of the Committee to talk to Mr. Williams after the hearing. David is an excellent example of what goes on into the process, into providing complex rehab.

In 1975, David was diagnosed with multiple sclerosis. This form of multiple sclerosis is characterized by acute exacerbations of the disease, resulting in the formation of scar tissue in various locations in the brain and spinal cord. This in turn causes a wide variety of symptoms.

In David's case, the location of the multiple lesions in his spinal cord have resulted in multiple symptoms and disabilities, including quadriplegia and multiple complex medical conditions.

The process of obtaining his wheelchair started with the thorough review of his medical record and complete and detailed evaluation by a multidisciplinary wheelchair seating clinic. Based on this evaluation, David's neurologist prescribed a power wheelchair and a seating system that would give him pressure management, respiratory relief when necessary, postural stability, abductor spasticity control and the ability to periodically reposition and elevate his legs.

The certified rehab technology specialist conducted an environmental assessment including his home, his workplace, and his vehicle. Based on the doctor's prescription and the recommendations from the various health professionals that were at the seating clinic, we ordered the following components to provide David with an appropriate wheelchair: a power wheelchair base, a transportation securement system, joystick-style driver control with tremor dampering, power elevating leg rests, and a power seating system with the following functions: tilt, recline, power elevating seats, lateral trunk supports, adductor positioning device, and a headrest.

To meet David's unique needs, the wheelchair he is driving today is built from components derived from seven different manufacturers. The component parts were assembled by a rehab technology company who had to fabricate some of the hardware needed to blend the different components into one system. A customized wheelchair system was then delivered to David, and several field adjustments were made during multiple visits to David's home.

The costs of all of these services that were provided are included in the base Medicare payment for the power wheelchair system.

Between the time David notified the staff of the seating clinic, the team assigned to his case had spent about 40 hours. This time includes doing environmental assessments, working with David to see what kinds of things he must do every day to maintain the best possible functionality and quality of life, ordering the components, assembling, fitting, adjusting the product and training David in the proper use of the system.

As the supplier, we also incur significant costs of obtaining all of the necessary complex medical documentation that Medicare requires. David's case is not unique. It represents the kind of challenge rehab technology companies see on a regular basis. Imposing a competitive bid process on complex rehabilitative services will substantially undercut the quality of services and the life for thousands of persons with disabilities and will essentially determine whether my business will continue or not.

If my company loses this bid, the impact will be far greater than just losing my Medicare business. I will likely lose most of my other business for those product categories, because referral sources prefer to refer the providers who can take care of all of their business, not just patients who have one particular payer.

In addition, State Medicaid programs and private payers will likely adopt the new lower Medicare bid fees, further negatively impacting any remaining business. Therefore, the majority of my business will be lost, forcing me to close my doors.

As a small business, I believe we are disproportionately negatively impacted by this bidding program.

There are two bills that have been introduced, H.R. 1845 and H.R. 2231, that would make reasonable changes to how CMS implements this bidding program, and it would begin to address some of the problems faced by small businesses.

I strongly urge this Committee to actively support these measures.

Thank you for the opportunity to be here today and I willbe happy to answer any of your questions.

ChairmanALTMIRE. Thank you, Ms. Gilligan.

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

ChairmanALTMIRE. I now introduce Ms. Georgie Blackburn. Ms. Blackburn is Vice President for Government Relations and Legislative Affairs for Blackburn's and has worked within the homecare industry since 1978.

Blackburns is an independent pharmacy and medical equipment and medical supply company with a staff of 150 people. Ms. Blackburn is the immediate past president of the Pennsylvania Association of Medical Suppliers and member of the American Association of homecare.

She is here on behalf of the American Association of homecare, which represents health care providers, equipment manufacturers, and other organizations within the homecare community operating in approximately 3,000 locations in all 50 States.

Welcome, Ms. Blackburn.

STATEMENT OF GEORGETTA BLACKBURN, VICE PRESIDENT, GOVERNMENT RELATIONS AND LEGISLATIVE AFFAIRS, BLACKBURN'S, TARENTUM, PENNSYLVANIA, ON BEHALF OF THE AMERICAN ASSOCIATION OF HOMECARE

Ms.BLACKBURN. Thank you, Mr. Chairman. We appreciate this opportunity to speak directly to you today, and the distinguished panel.

The American Association of Homecare represents durable medical equipment providers and manufacturers who are part of the continuum of care that assures that millions of seniors and disabled Medicare beneficiaries receive cost-effective, safe, and reliable homecare equipment and services in their homes.

It is essential that Congress examine the Medicare competitive bidding program and its impact on patients and on small providers.

The Association is very concerned about the effect that competitive bidding would have on the survival of small homecare providers and also on the ability of providers to meet the needs of their patients.

A typical beneficiary using home oxygen, which is a life sustaining therapy, is a woman in her seventies who suffers from late-stage chronic obstructive pulmonary disease, COPD. COPD is a debilitating disease characterized by low levels of oxygen in the blood and severe air flow limitation resulting from inflammation of the airways.

Medicare beneficiaries who use power wheelchairs are seniors and Americans with disabilities who have lifelong debilitating conditions such as multiple sclerosis, Lou Gehrig's disease, cerebral palsy, traumatic brain injury and spinal cord injury. A power wheelchair enables individuals to live at home independently rather than in a more costly constitutional setting.

Mr. Williams' chair, as Ms. Gilligan stated, is a prime example of complex rehab power mobility, and Mr. Williams exemplifies the independent, high-functioning beneficiaries we service.

Blackburn's has had a very difficult but not unique experience with the bid process. As you mentioned, we are in the Pittsburgh CBA. We struggle to submit bids on all nine product categories. The bidding system is complex, and it is confusing.

Medicare expected 16,000 providers to submit bids. Mr. Wilson stated 6,300 certified bids were received. My feeling is many providers looked at the convoluted program and chose not to bid at all.

Under the first round of the bidding program, providers submitted bids to CMS to provide items and services at a reduced reimbursed rate. Providers who meet Medicare participation requirements and whose bids are deemed low enough will be selected as contractors.

Those who are not selected as winning contractors will not be able to provide competitively bid equipment or services to Medicare beneficiaries. Since Medicare payments typically comprise 35 to 50 percent of a small providers's revenue, losing the ability to provide competitively bid items for a 3-year contract period is essentially a death knell.

The risk that this program poses to homecare providers cannot be overstated. If our company is not selected as a contractor, our very survival is in jeopardy.

The competitive bidding rules designed by CMS are stacked against small providers. Small businesses lack the economy of scale to negotiate lower prices for manufacturers and the physical size to cover an entire CBA, the area of the bid.

Even with the small business protection, such as the ability to form networks or the 30 percent set-aside, the program will still radically reduce the number of providers that exist today.

The American Association of Homecare believes that the changes to the program contained in H.R. 1845, the Durable Medical Equipment Act of 2007, are critical. This bill will protect homecare patients and give a fighting chance to small providers. And we thank the Subcommittee members for your overwhelming support of this legislation.

H.R. 1845 does not repeal competitive bidding; rather, it makes sensible changes to ensure patients access to home medical equipment, while protecting small providers.

Specifically, the legislation would accomplish the following:

First, it exempts smaller rural areas from competitive bidding. Congress gave CMS the authority to exempt areas with low population to ensure that bidding is not implemented in areas that lack a sufficient number of providers.

Second, under H.R. 1845, all providers who meet Medicare participation standards and who submit a bid would be allowed to continue to provide equipment and services at the lower competitively bid rate. This provision restores fairness for small providers and would ensure that beneficiaries have choice.

Third, the bill would restore the rights of participating providers to administrative and judicial review. Presently, homecare providers have no recourse if a mistake is made by CMS in calculating the award reimbursement rate or in awarding a contract. An error can result in the loss of a bid, and more importantly, the loss of a business.

Fourth, the bill exempts items and services unless savings of at least 10 percent can be demonstrated. CMS should be required to show the competitive bidding saves money.

The American Association of Homecare believes that unless it is modified, the Medicare competitive bidding program will undermine our Nation's homecare infrastructure. It will also jeopardize patients' care, choice of providers, and access to the medical equipment and services they desperately need.

I look forward to working with this Committee and its staff to address small business issues and would like to continue to work with Committee members to enact H.R. 1845.

Thank you so much for the opportunity to testify today.

ChairmanALTMIRE. Thank you, Ms. Blackburn.

[The prepared statement of Ms. Blackburn may be found in the Appendix on page 97.]

ChairmanALTMIRE. I now introduce Richard Saxon. Mr. Saxon is President and CEO of BioMedical Life Systems, Incorporated, a manufacturer of portable electrotherapy devices and accessories founded in 1983. BioMedical Life Systems focuses on the development and manufacturing of durable medical equipment.

Mr. Saxon is a member of the Advanced Medical Technology Association, AdvaMed, which represents more than 200 small and large businesses producing medical devices, diagnostic products, and health information systems throughout the country.

Welcome, Mr. Saxon.

STATEMENT OF RICHARD SAXON, PRESIDENT AND CEO, BIOMEDICAL LIFE SYSTEMS, INC., VISTA, CALIFORNIA, ON BEHALF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

Mr.SAXON. Good afternoon. My name is Richard Saxon, and I am President and CEO of BioMedical Life Systems, a small business manufacturing durable medical equipment, based in Vista, California. I thank the Committee for inviting me to testify on behalf of AdvaMed at this important hearing today.

AdvaMed represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products, and medical information systems.

Over 70 percent of our members are small companies with sales under 30 million per year. AdvaMed members are devoted to the development of new technologies that will allow patients to lead longer, healthier, and more productive lives.

The medical technology industry is filled by intensive competition and the innovative energy of small companies, firms that drive very rapid innovation cycles amongst products, in many cases heading to a new product version every 18 months.

The medical device industry has developed a wide range of DMEPOS products to meet the many needs for many complexconditions. Access to DMEPOS can often mean the difference between a patient being able to remain at home or being admitted to a more expensive treatment in a nursing home or hospital.

The primary focus of a competitive acquisition program is cost savings. Under such a program, my industry has strong concerns about the potential impact on quality of care and patients' access to lifesaving and life-enhancing technologies that companies like mine develop.

The competitive acquisition program will limit the number of suppliers serving Medicare beneficiaries. It will encourage the smaller number of suppliers to limit devices to those that meet the average basic patient's needs. We feel that patients who have those special needs, those special needs will not be met.

This program will significantly impact companies like mine that manufacture devices to meet all levels of individual patient's needs, including innovative and unique technologies.

It will also directly impact companies working to modify highly complex technologies that are currently used in the hospital so the patients may successfully use them in a homecare setting.

It could also dampen the significant investment my industry makes in research and development, R&D. If the program reduces payments to a point where innovative devices cost more than the payment amount, the incentive to reinvest in additional R&D is eliminated and the patients will suffer.

When Congress established the competitive acquisition program in 2003, AdvaMed recommended a number of safeguards to ensure beneficiary access to products prescribed by their physicians. We appreciated the establishment of the Program Advisory and Oversight Committee, PAYOUT, to allow for stakeholders' discussions about program implementation.

We believe it has been a helpful tool.

However, given the likely impact of the program on daily patient care, we believe that there are still many details warranting careful consideration.

We appreciate your willingness to listen to our concerns and to work with us to ensure that Medicare beneficiaries continue to receive high-quality DMEPOS. My written statement provides details, but let me highlight a few actions that should be taken by Congress or CME.

Congress requires CMS to report on the program by July the 1st, 2009. We ask that CMS be required to accept public input to ensure the reports analyze clinical outcomes, quality measures, measures to assess beneficiaries' access to the range of effective technologies, and potential impact on other Medicare services such as hospitalizations that are a result of the competitive bidding program.

We have strong concerns about CMS' ability to use bid amounts submitted in one MSA to set rates in another 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 to ensure that the payment amounts reflect local market conditions.

The product categories used by CMS and the individual codes within these product categories are often broad, and fail to adequately differentiate between products with diverse and wide ranges of quality, functionality, technology and clinical utility.

If the accepted bid amount does not reflect the various costs of the range of products, beneficiaries will not have access to the full range of products within a category or code.

We urge CMS to allow for public comment on the categories and codes being bid.

Thank you, again, for holding this important hearing. We look forward to working with this Committee on ways to make sure that beneficiaries maintain access to quality care, medical technologies, as the program continues to be implemented.

Thank you.

ChairmanALTMIRE. Thank you, Mr. Saxon.

[The prepared statement of Mr. Saxon may be found in the Appendix on page 104.]

ChairmanALTMIRE. Now we turn to Mr. Jose Navarro. He is a pharmacist and owner of Navarro Discount Pharmacies in Florida. Navarro Discount Pharmacies is currently a chain of 20 drug stores and is currently the top drug store in the Nation.

Mr. Navarro sits on the Board of the National Association of Chain Drug Stores, which represents more than 200 chain pharmacies throughout the Nation.

Welcome.

Mr.NAVARRO. Thank you.

STATEMENT OF JOSE F. NAVARRO, RPh, NAVARRO DISCOUNT PHARMACIES, MEDLEY, FLORIDA, ON BEHALF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mr. Altmire, Ranking Member Gohmert, Congressman González.

Regardless of the size of the members of NACDES, which range from 4- to 6,000 stores, all members are deeply concerned about the impact of patient access and the competitive acquisition problem it will have.

Many beneficiaries obtain their supplies from local pharmacies. In fact, a study found that nearly two-thirds of all of older diabetic patients obtain their diabetic test strips from retail-based community pharmacists.

Retail pharmacists are the largest provider of medical equipment and supply services to the Medicare patients. And in many cases, the pharmacist is the most readily accessible health care provider in the community for Medicaid beneficiaries.

We offer the following four suggestions to improve the competitive acquisition program to ensure continued participation by pharmacists servicing Medicare patients.

First, State-licensed retail pharmacists should be exempt from accreditation requirements. The competitive acquisition program requires suppliers to be accredited before they are awarded a contract. The goal of these requirements is to reduce fraud, waste, and abuse to the Medicare program.

While requiring accreditation of pharmacists is unlikely to reduce fraud, waste, and abuse, it will have the results of reducing the numbers of pharmacists that would be available to supply durable medical equipment and supplies to the American beneficiaries.

The costs associated with the accreditation processes, which can amount to several thousand dollars and hundreds of man hours for each pharmacy, creates a tremendous disincentive for pharmacists to participate.

I would like to clarify for a minute the number of 2,200 that was stated before, which Mr. Wilson did not know about it. That number comes from a program adviser on Oversight Committee for CMS in a meeting of October 11, 2007, in Baltimore, Maryland.

The timing and extensive paperwork required by accreditation requirements is likely to be blamed for this low turnout, and, as a result, our seniors may face difficulties in obtaining essential medical equipment and supplies.

Further, requiring accreditation of State-licensed pharmacies is necessary. Pharmacies and pharmacists are licensed by the board of their respective States to provide services to patients. This very important feature allows pharmacists to bring a great degree of integrity to the Medicare program.

Second, diabetic testing supplies sold at retail pharmacists should not be subject to competitive acquisition. Currently Medicaid beneficiaries can obtain the diabetes glucose monitoring and testing strip from retail pharmacies that participate in the program, allowing the beneficiaries to obtain their equipment, supplies

and prescription drugs for managing their diabetes from qualified pharmacists.

Evidence for programs such as the Ashfield Project prove that the pharmacist-based programs can result in clinical significant improvement to the health outcomes of diabetic patients.

Further, unlike DME supply, CMS did not evaluate the effects of competitive acquisition on diabetic supplies during the competitive bidding project. Those expansions of the competitive acquisition program to diabetic supplies sold at retail pharmacies would create significant confusion and frustration in diabetic providers.

And if you look at Mr. Wilson's testimony, the problems are mainly based on very expensive equipment like wheelchairs, oxygen equipment. At no point was the point of diabetic strips brought up by him. Also the fraud issues that he mentioned through his presentation were not related to diabetic supplies.

Fourth, State-licensed and retail pharmacists should be exempt from CMS proposed surety rule. In addition to the competitive bidding program, CMS also proposed to require $65,000 surety bond program for all Medicare and medical equipment supplies. For many pharmacies this will be more—this will represent almost over $2,000.

According to CMS' own calculations, up to 15,000 DMEPOS suppliers currently enroll in the Medicare; 22 percent are in rural areas, who will cease to provide Medicare beneficiaries as a result of the surety bond.

CMS envisioned that most, if not at all, of the Medicare business conducted by DMEPOS suppliers will be assumed by other medical equipment and supplies remaining in the program. We really contest that. I think that is an incorrect figure.

Clearly, CMS has indicated that these proposed rules will result in even fewer pharmacies participating in the Medicare Part B program. As a result, patients could face tremendous difficulties in obtaining the necessary equipment and supplies.

The last one is that we will ask that CMS does not create national original competitive acquisitions area for mail order. CMS has stated that for the year 2010 and thereafter, he has the authority to establish national regional competitive acquisitions areas for supplies that furnish items through mail order. As I have already shared with the Committee, the majority of older patients prefer to obtain DME supplies through their local pharmacy, and this will impede that.

In conclusion, I am grateful for the opportunity to testify before you today. Thank you for providing a forum to air our concerns on the medical equipment and supplies acquisition program.

ChairmanALTMIRE. Thank you.

[The prepared statement of Mr. Navarro may be found in the Appendix on page 109.]

ChairmanALTMIRE. We will do at least two rounds of questioning from each of the members here.

I want to start with Ms. Gilligan. Can you share with the Committee your thoughts on some of the modifications CMS in its final rule to address concerns raised specifically by small suppliers?

Ms.GILLIGAN. Yes, Mr. Chairman. I would reference you to my written testimony in the record for additional details, but I have a couple of concerns.

First of all, CMS established a network scenario that is theoretically geared to help small business, but the logistics and the legal issues associated with that scenario make it unlikely that any small business could pursue that approach. I don't know of any myself, and I have heard testimony this afternoon that not many people do know.

Secondly, CMS sets a target that 20 percent of the suppliers be small business. But then, again, the low bidders who are forced to accept the bid amount would most assuredly have to take a financial loss on their product category.

And I will give the example. In my marketplace I have large competitors. And if small business is targeted that will give us one or two small businesses. But because of the buying ability of the large business, the small business, even if offered the ability to take it at a lower price, we can't buy it at that price and we can't compete. So it is not really access.

So I would say despite these modifications, I don't believe that CMS has taken any meaningful steps to address the special needs of small business and our ability to participate in this program.

I think those who have a small business, like myself and all of the panel at the table here today have, a clear case of grievance under the Regulatory Flexibility Act which provides Small Business Administration with the authority to raise issues of unfair government, such as the CMS imposing right now.

I was hoping that with the regulatory impact on small businesses being disproportionate, that you could help us out today and work with us on the Regulatory Flexibility Act.

ChairmanALTMIRE. Thank you.

I want to say for the record that I do agree with Ms. Gilligan about the need to protect our small businesses and the beneficiaries they care for.

The Regulatory Flexibility Act was intended to encourage agencies such as CMS to tailor regulations to be less burdensome to smaller entities, like these small suppliers, under DME competitive bidding.

I am concerned that given the magnitude of this program, that CMS has similarly failed to address the requirements of the Regulatory Flexibility Act in isolating the impact that a rule will have on small businesses.

In the absence of a rigorous analysis of this rule and the impact on small businesses, this Committee cannot be certain that small suppliers can compete or that rural beneficiaries will not have difficulty obtaining DME.

So I appreciate your answer.

And I would now ask, Mr. Saxon, in your statement you recommended that CMS should be required to conduct bidding to set prices within all MSAs as it expands the program, essentially prohibiting the agency from using bid amounts determined in setting payments in one MSA to set rates at another MSA.

Why do you feel this is important?

Mr.SAXON. Mr. Chairman, the cost of doing business in different parts of the country are undeniably always different. The cost to rent a building in New York is certainly different to a supplier renting a building in a rural area.

CMS should conduct bidding in each MSA with the local suppliers to establish the prices within that specific MSA. They should not simply be transferring a bid amount from one MSA, assuming that would be good for the whole country as far as moving it from one MSA to another.

As you know, and I will just point out, the cost of doing business in one State or one MSA are very different. So the prices should be set locally to ensure the programs meet the needs of the patients in that area.

I think that it is a fairly logical thing that one should not allow CMS to be able to establish what works in one or what is established for one MSA cost and just transfer that across.

ChairmanALTMIRE. Thank you.

My last question for the first round is for Ms. Blackburn.

Given your experience in serving Medicare beneficiaries, what would you anticipate the impact of this program would be for patients and their caregivers, and what kind of education will Medicare beneficiaries and suppliers need?

Ms.BLACKBURN. That is a good question, Mr. Chairman.

We know there will be a problem. We know that there has been no education. When the Drug Act came about last year, we know when the—we know when the drug act came about, the Medicare drug act came about, there was a huge amount of information that was shared with the public as well as caretakers who take care of people who are on medications.

We have seen none of that with competitive bidding. We have very little information to handle the bids ourselves. There is just not a lot of information out there.

As far as the patients, what they need and their caretaker, we feel that the impact will be, if you look at the market, the impact may be if you have a growing demographic and you have less suppliers to provide to that demographic, we suspect that the quality of care will be at risk.

And we are concerned that the type of services we provide now—those of us who are in that business, that you could call us 24 hours a day—just may not be there, because the award winners will be working on the basis of volume.

So how that will impact on the caretakers, I am not sure. But I will say there will be a higher level of frustration for those that care for those at home.

ChairmanALTMIRE. Thank you.

I will turn it to Mr. Gohmert.

Mr.GOHMERT. Thank you.

Mr. Navarro, thank you for providing the information on the 2,200. I will see that gets passed on to Mr. Wilson so he will know what came from his agency in the future.

Mr.NAVARRO. Thank you.

Mr.GOHMERT. And I have a good deal of rural area in my district, and it has been an increasing concern. It looks like someone has to go toward almost complete elimination of people in retail, so that

you basically can watch television, decide what your symptoms are and which commercial best fits your situation, and then get on the Internet or telephone and order whatever pill you want and what other orthotic piece of equipment looks appropriate. But we know that we need help. That is why people get licenses: doctors, health care providers. So I am very concerned that we are about to lose one of those elements.

Of course, CMS wants accreditation. They have got these procedures.

Let me just throw the question out to each of you as to whether or not the public would be adequately protected without this particular accreditation procedure, or if there is something that would not be quite as onerous?

Yes, Dr. Taubman.

Dr.TAUBMAN. Thank you, Mr. Gohmert.

I think from the physician's standpoint, physicians go through rigorous education, training, licensure. That is a significant burden to get through that process.

Mr.GOHMERT. That is why we have prescriptions, is because you are supposed to know more what we need than we do.

Dr.TAUBMAN. I would agree with you, sir.

So I would submit to you, as I said in my testimony, that I believe physicians to be exempted from the accreditation process because we have already proved that we are capable of dispensing and prescribing these items for our patients by virtue of our licensure and our training.

I also want to point out to you, in case you didn't know, I happened to download from one of the deemed accrediting organizations, the standards manual, which is 128 pages long, that I am supposed to follow to become accredited.

I would submit to you, as a small business person in a small practice with six employees, the burden for me to comply with this is nearly impossible. And I think most physicians who supply DME at the point of care for our patients, would be unable to do this, and we are not going to be able to give these devices to our patients.

Mr.GOHMERT. I may need to get a copy of that downloaded, too, so we can provide that to Mr. Wilson, because apparently that is a little more than 14 I think we were talking about earlier.

Mr.SHIRVINSKY. We do support accreditation for DME companies. And here is why.

The CMS testimony today spent an inordinate amount of time talking about fraud, and they paint a very—they painted a picture with a very broad brush that made this entire industry appear corrupt.

Mr.GOHMERT. And you are not?

Mr.SHIRVINSKY. We are not. And we strongly object to the way they utilize the data on fraud.

Now, if they want to look at fraud, you have got to take a look at some situations like Miami, where 40 companies were given provider numbers inside of a burned-out, closed-up strip mall. You cannot bill for Medicare without a provider number. You cannot get a provider number without CMS or their subcontractors coming in

and verifying that the business that is applying for a provider number is a legitimate operation.

Obviously, something is wrong. I mean, CMS has let a lot of companies slip through the cracks. Whether there are payoffs or kickbacks or bribes that are involved, I don't know. But something is terribly wrong when that number of companies can appear at a single address and bill millions upon millions upon millions fraudulently to the government.

Mr.GOHMERT. So you think we need an accreditation process for CMS?

Mr.SHIRVINSKY. I think accreditation for process for CMS would be a good idea at this point.

But accreditation is a good idea for this industry. All it means are people are abiding by the rules. They are following the law. That is what we try to do with our members as an association. That is what the national organization does as well. That is what State by State, organization by organization, company by company, tries to do.

Mr.GOHMERT. You think the accreditation process as it is too onerous, or you think it is about right?

Mr.SHIRVINSKY. Most of our companies have no problem with the accreditation process.

Mr.GOHMERT. Apparently some that don't have problems should have problems.

Mr.SHIRVINSKY. That, I can't speak.

All I know is the companies in my organization that are accredited do not complain. I have never heard one complaint from my companies about the accreditation process or accrediting companies.

I do know that a lot of hospitals, for example, take issue with a lot of the accrediting companies. Our people have been able to work with them. They worked very hard. Our companies worked very hard to comply with the law. And a lot of the violations that appear when CMS, their subcontractors, conduct audits, we are normally caught in the middle. If an audit is done today, it is likely to find some violations. But the violations won't be something that our company did. They will likely be in what is contained in the physician's order. Again, we are in the middle.

Mr.GOHMERT. Let me hear from other witnesses.

Ms.GILLIGAN. I also agree with my partner here. I am in the State association in Ohio. And we already have licensure in the State of Ohio for accreditation, and you cannot dispense life-sustaining equipment or technology, sophisticated technology equipment in Ohio,

Mr.GOHMERT. Is your mike on?

Ms.GILLIGAN. You cannot dispense life-sustaining equipment or technologically sophisticated equipment in Ohio without a license, but we do exempt physicians because they already are licensed and all of those things.

And I do applaud, and I do like requiring credentials, and I do like the accreditation process, because I think it makes me have a better company. I am very proud of that. We went through a lot of work to do that, and we put in a lot of practice, and it is very expensive and time-consuming. And I think we have a better end

product. And with that, the customers and the public benefits from that.

And I think that we should have it, but I don't think it is a solution to fraud and abuse that CMS is using. It is, absolutely, bad people are going to do bad things. They are going to lie. They are going to write bad things.

Fraud and abuse is not accreditation. Accreditation is raising the level of care and the quality, which is what we should all be wanting to do for our patients. It is not to keep out the bad people. They will just lie. Bad people are bad.

Ms.BLACKBURN. The American Association of Homecare does support accreditation. We also feel it raises the bar for the companies and it gives an even playing field for how things are done within each firm.

We have actually asked CMS to announce a final date for accreditation, and that has never been forthcoming. This has been going on all year.

On a personal level, I can tell you that Blackburn was accredited in 1995 by the Joint Commission. Is it difficult? It is a little tedious. You do have a manual to follow. There are some things that are introduced into your business that you may not have thought about that, absolutely, it gives that business the ability to improve through the accreditation process.

And I also agree that the end result is a help to the patients whom we serve.

Mr.GOHMERT. Thank you.

Mr. Saxon.

Mr.SAXON. Well, from the manufacturer's side, admittedly, few of the smaller DME manufacturers will be endeavoring to bid for equipment under the competitive bidding program. But I would say that—I leave it to the Association of Homecare and other people here on the panel, since they are representing more of the suppliers, which are the people that are asking to be accredited.

So I won't go any further in this matter.

Thank you for the opportunity.

Mr.GOHMERT. Mr. Navarro.

Mr.NAVARRO. I am here, you know, I can tell you from a pharmacy. Today, pharmacists are highly educated individuals. They go through 6 years of higher education plus 1 year of training. They are licensed by the State Board. Pharmacies and pharmacists are licensed by the State and, really, there is no need to offer an accreditation program for pharmacists. I mean, we go through that, and we—on top of that, we are—we have continuing education every year. I do not see a need why we should go through an accreditation program when we are licensed by the State and audited on a weekly basis.

And just tell you, with regard to the fraud that Mr. Wilson said—and I am from Miami—really the fraud has to be blamed on CMS. I mean, the licenses, the fraud is happening with storefront locations that get patients recommended, that then they open their own DME stores. I mean, these are licenses that should never have been granted. You know, they do not visit the location for an inspection.

And then they complain there is fraud. And at the same time, they want pharmacist accreditation for us to get a license. They go in and inspect us. They inspect us every year and they issue a license.

I don't think pharmacists require accreditation.

Mr.GOHMERT. Thank you very much.

ChairmanALTMIRE. Mr. González.

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

When we think of DME suppliers and vendors, I don't know, we envision doctors and pharmacists. And when we look at the grand scheme of what CMS is trying to do, we are not sure how that impacts manufacturers and such. But you are all up here and you are all expressing your deep concerns about the negative impacts from where you operate and how you take care of patients in your own right.

Mr. Navarro, I visited a small pharmacy in San Antonio; the father and the daughter, the daughter that followed in the father's footsteps.

I know what you described. But if this went into effect, there is no way that Ortiz Pharmacy is going to be able to prevail. And I know Mr. Wilson told me that they are going to make exceptions somehow within that San Antonio area, maybe somehow within that CBA, to accommodate someone like the Ortiz family and the Ortiz Pharmacy.

How do you see it playing out?

Mr.NAVARRO. We have 20 stores so we have a decent number of employees and supporting staff and a warehouse.

We were not able to do the accreditation. Okay. At the end, we were going to go out to hire a firm to do accreditation for us, and it was impossible. We could not do it. And we, you know, we are pretty sophisticated. We are in the top pharmacies in the Nation and really we were not able to complete that—and Ortiz pharmacies will not survive. I don't care how many exceptions they do and how many things they do; at the end, I will guarantee you the community pharmacist, the independent pharmacist and many small pharmacists will not be able to participate in this program.

And just one more second. I cannot really imagine how an older lady will get the test strips and medication to measure those test strips without consultation with the pharmacist. That is why it is beyond my mind to go on the Internet and get it.

Mr.GONZÁLEZ. I think any member has a pharmacy like I described in their town and such, and thank God that we have them. If I told you to what extent they go to serve their clients, it is extraordinary. It is just beyond belief. To lose that would be a true tragedy.

Mr. Saxon, you are from the manufacturer and device maker and those people, and I wonder how does it impact you?

I did pose a question about—from what I learned about how to categorize things first, which could limit choice. Then obviously limiting the number of vendors could very well impact what would be available to that user, to the patient, to the beneficiary.

How does that play out as far as unique type of DME? And all of it is important. All medical equipment supplies are important one way or another. But some are unique. They are a little more

sophisticated, need more instruction, and so on. And that is what I am talking about.

What could be the potential negative impact on, one, the availability because of choice and such, of these products for patients, beneficiaries?

Mr.SAXON. The first thing that I think is important to note is that this bidding contract is for 3 years. So any new innovative products that come into the market and try and obtain a HCPC code and category will have to wait 3 years. And even then, it will take time for them to be able to establish to CMS that this is a proven technology.

So this is one issue.

The other issue is that there has to be accountability in the categories and codes that are the HCPC codes that CMS establishes for different types of sophistication of devices. We can have, for example, in wound care, whereby a patient is treated with gauze and ointments, and that patient can be having to have those gauze and ointments treated, put on daily, and/or we can look at offering a more sophisticated DME product that allows for a more likely success of treatment in a short period of time.

And I have to point out, these people are elderly. They are 65 and older. These people are generally given and take what they are presented with. They are not likely to say okay, that is not what I wanted or that is not what I believe I should be treated with. They are given the equipment that Medicare decides they should have, whether—and it is probably, under this program, going to be the least expensive basic treatment equipment, and they are going to not be able to compare it with other treatments that are available or on the market.

It is very important that we ensure that Medicare, under this bidding program, takes account of the total cost of the treatment. I mean, you can get a more expensive device, treat the patients, and successfully treat the patient, or you can prolong that treatment. And then you are involved with daily dressing or whatever is necessary to prolong that cheaper means of treatment. But in the end, the cost to Medicare will be greater than if they initially supplied the more expensive equipment.

So there has to be accountability somehow that the codes allow for different sophistication of treatment if they are needed, and that it is not just the basic and everything bundled together in one HCPC code. And then, of course, it is going to be the cheapest product, because that is the way—it is a bidding system, and that poor patient then is going to suffer.

This is talking about costs, first of all, but also the suffering of the patient having to wait for this treatment period of time to be successful.

I mean, if you talk about wound care, you are talking about bed sores in particular, but you are also talking about other areas of wound care. I mean, they use wound care for—

Mr.GONZÁLEZ. I appreciate it, Mr. Saxon, and my time is up and I yield back.

ChairmanALTMIRE. Mr. González, I would say that we are not planning to ask more questions. But if you do have one more, you can ask it.

Mr.GONZÁLEZ. Dr. Taubman, is that correct? Do you know Dr. Larry Harkus?

Dr.TAUBMAN. I know him very well.

Mr.GONZÁLEZ. He is a good friend, dear friend in California.

I would like to play out one scenario, and we also have to think in terms of the Medicare beneficiaries, whoever that may be—yourself or your mother or father or whoever—going down to Mr. Navarro's pharmacy or the Ortiz Pharmacy and suddenly finding out they are not going to get that particular DME. So where are they going to go? And we have to start thinking that through.

Now from a physician's point of view, my mother goes to you, and soon I will be going to you, and I will be covered, regardless. My mother is a beneficiary. She goes over there and, because of the new rules and the new model and such, you are not going to be able to provide her something as basic as this boot that you are referring to. So where is my mother going to go? From your office, where are you going to make my poor mother go?

Dr.TAUBMAN. Let us play that out, and we will use my walking boot that I brought here today.

The way the regulations are written, currently CMS did in their recent final role, exempt some products from the competitive bidding. And also, in fairness to them, they did say that all physicians could supply these products at the point of care.

They were things like walkers, those metal four-poster things you see people with. Canes, crutches, and manual wheelchairs are some things that I could give out to my patients if need be.

But let us talk about your mom who comes to see me, and I practice in Maryland and it gets icy and it snows. She has a fracture that is unstable, and I am now seeing her in my office, but because this item, which is an off-the-shelf orthotic, and as Mr. Gohmert said, only PTs or OTs are allowed to dispense those without competitive bidding, I as a doctor can't do that.

So I say to her, you know what? I am really sorry, but I will give you a set of crutches, and you can walk across the ice with your crutches, get on three buses and go across town and get this item from a larger supplier.

I am not sure that is exactly what Congress intended in this process here. It is certainly not good medical care. So I think in that scenario we are talking about a very serious problem for physicians at the point of care.

Physicians are not dispensing through their office power-operated wheelchairs. We are not dispensing hospital beds. We are not dispensing oxygen tanks. We are not dispensing CPAP machines that are used for sleep apnea, and all of the things that are larger cost items. And clearly these folks are much better equipped to do that than I as a doctor in my practice.

But these items are things we are not going to be able to dispense, and it is going to impact care; and from that standpoint, it makes no sense whatsoever to include physicians in this particular process for these items that we dispense as a critical part of our care at point of care.

Mr.GONZÁLEZ. Thank you very much.

I yield back.

ChairmanALTMIRE. I want to thank the panel. You all came in from out of town, and at some expense and travel, and I really appreciate it. The Committee appreciates the fact that you took the time to join us today and offer your expertise on this very important issue. We are going to continue to study this, and we ask for your consideration and help in moving forward in offering your expertise.

So thanks to each and every one of you.

I ask unanimous consent that members of the Committee have 5 days to submit statements and supporting materials for the record. Without objection, so ordered.

And this hearing is now adjourned.

[Whereupon, at 4:20 p.m., the Subcommittee was adjourned.]

STATEMENT
of the
Honorable Jason Altmire, Chair
Subcommittee on Investigations and Oversight of the
House Committee on Small Business
Hearing on the
"Competitive Bidding for Durable Medical Equipment: Will Small Suppliers be able to Compete?"
Wednesday, October 31, 2007

This hearing on "Competitive Bidding for Durable Medical Equipment: Will Small Suppliers be able to Compete?" is now called to order.

As more baby boomers age into Medicare, few would disagree that reforming the public program is necessary. But change presents unique challenges for the program, its beneficiaries, and the medical providers that support it. That's why changes to Medicare must be made carefully and with a great deal of thought and input.

Today's hearing will shed light on the importance of small durable and medical equipment suppliers to the Medicare program. It will allow the Subcommittee to fully understand the implications of a project that affects both small health care providers and patient's access to care. Small firms are an essential part of Medicare and fill gaps larger businesses either cannot or will not fill.

On April 2nd, the Centers for Medicare & Medicaid Services issued its final rule on competitive bidding for durable medical equipment. The program allows Medicare to award contracts for durable medical equipment to suppliers with the lowest bids.

CMS maintains that the program will not only ensure beneficiary access to quality medical supplies and services, but will also reduce beneficiary out-of-pocket expenses and improve the effectiveness of payments.

The question remains "What will competitive bidding mean to the small business community?" And do its benefits outweigh its costs? CMS has estimated that within five years of implementing the program, the savings to taxpayers will exceed over $1 billion annually. The potential for gain cannot be ignored, but these reforms could have enormous ramifications.

While the objective is to reduce costs, it is not clear that the new competitive bidding program will achieve this goal without unraveling the DME small business community. Small suppliers make up well over 90 percent of the nation's medical equipment providers.

To its credit, CMS appears to acknowledge the value of small firms to the DME marketplace. And the program pays deference to this importance by putting in place rules that protect certain categories of small suppliers. It also encourages the formation of small supplier networks in its final rule. But these actions seem to provide little relief for most small suppliers.

By CMS' own estimation, once the competitive bidding program has taken full effect, as little as 20 suppliers on average will be initial bid "winners" in each area. Even with small business protections in place, few small firms can expect to be actual bid "winners." This may spell ruin for small providers whose revenues are often less than a million dollars a year.

What seems clear about CMS' competitive bidding program is that the only businesses certain to survive the Agency's payment reform will be national suppliers. Small businesses may be the backbone of this country; but the manner in which the competitive bidding program is structured challenges their very survival.

This issue is of particular concern to me because Pittsburgh is one of the first ten areas to implement competitive bidding. I worry that CMS has not considered the unintended consequences that may result from this program, including the possibility that patients may lose the personal relationship they have developed with their local provider, in turn compromising their quality of care. Further, I have concerns that western Pennsylvania will be disproportionately impacted by competitive bidding, and that it may force some local small businesses to close their doors and working families to lose their jobs.

Congress must take a long look at competitive bidding and the impact it will have on small suppliers. Though there is little doubt that Medicare must be reformed, in my view, small businesses should not shoulder that burden. The panelists here today are well-equipped today to talk about reasonable ways to ensure this does not occur.

I look forward to today's testimony and thank the witnesses for their participation. I would yield to Mr. Gohmert for his opening statement.

Opening Statement of Ranking Member Louie Gohmert
House Committee on Small Business
Subcommittee on Investigations and Oversight
"Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)."

October 31, 2007

Good morning and thank you all for being here as we examine the Centers for Medicare & Medicaid Services (CMS) Medicare Competitive Bidding Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. I would like to thank Chairman Altmire for holding this hearing and each of the witnesses for taking the time to provide this committee with testimony.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173). This legislation produced the largest overhaul of Medicare in the public's health program's 38-year history.

Among other things, the legislation required CMS to use competitive acquisition procedures when entering into contracts for durable medical equipment, prosthetics, orthotics and supplies under Medicare Part B. A single payment amount for each item derived under the new competitive acquisition project through competitive bidding will replace the current payment amounts. The new competitive acquisition project is the subject of today's fact finding hearing to acquire a better understanding of the CMS competitive acquisition's project definition and impact on small business medical suppliers. In developing the competitive acquisition project procedures relating to competitive bidding and the awarding of contracts, the CMS is required by legislation to take appropriate steps to ensure that small business medical suppliers have an opportunity to be considered for participation.

The legislation does not require the demonstration to be subject to the Federal Acquisition Regulation (FAR). FAR Part 19 implements Federal government policy to provide maximum practicable opportunities in its acquisitions to small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Such concerns must also have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency, consistent with efficient contract performance.

Competition is the foundation of capitalism. Competition stimulates innovation, encourages efficiency, and drive down prices saving taxpayer dollars. Small Business has historically been the engine of innovation and a catalyst for competition. They also employ more than 50% of all employees.

While I support competition and the outcomes it normally produces, I want to ensure that the competitive acquisition project's design methodology meets the intent of the Small Business Act by providing small business medical suppliers the maximum practicable opportunities to participate in the competition as both prime contractors and subcontractor. Additionally, it is imperative that we look at the big picture and make sure that the folks who need these services are getting the best quality of care they can. I think that is something that is oftentimes overlooked in Congress. We should not get overly caught up only in the numbers, but look to how the rules and regulations that our federal government implements affects the folks back home in our districts.

We have excellent witnesses here today to provide us with insight into the rationale behind the competitive acquisition project's definition of a small business medical suppliers and how the project's competition methodology ensures maximum practicable opportunities for them. I look forward to their testimony. Thank you Mister Chairman and I yield back the balance of my time.

TESTIMONY OF

LAURENCE D. WILSON

DIRECTOR, CHRONIC CARE POLICY GROUP

CENTER FOR MEDICARE MANAGEMENT

CENTERS FOR MEDICARE & MEDICAID SERVICES

BEFORE THE

HOUSE SMALL BUSINESS COMMITTEE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

ON

DURABLE MEDICAL EQUIPMENT, PROTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) COMPETITIVE BIDDING PROGRAM

October 31, 2007

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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
On
DMEPOS Competitive Bidding Program

Good morning Chairwoman Velazquez and distinguished members of the Committee. 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 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, and ensure beneficiary access to high quality DMEPOS items and services.

Overview

CMS is the largest purchaser of health care in the United States, serving over 92 million Medicare, Medicaid, and SCHIP beneficiaries. Medicare alone covers roughly 44 million individuals, with total Medicare benefit outlays projected to reach $454 billion in Fiscal Year (FY) 2008.[1] Each year, DMEPOS suppliers provide items and services including power wheelchairs, oxygen equipment, walkers and hospital beds to over 10 million people with Medicare. Reasonable Medicare payment amounts for DMEPOS are especially important considering the dramatic growth in expenditures for these items.

Medicare traditionally pays for DMEPOS items and services using fee schedule rates for covered items. In general, fee schedule rates are calculated using historical supplier charge data that may not be reflective of an appropriate payment amount for today's market. As the following chart illustrates, relying on historical charge data has resulted in Medicare rates that are often higher

[1] Department of Health and Human Services, Budget in Brief: FY 2008 at 51.

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.

Comparison Prices

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

Much of the growth in Medicare expenditures can be attributed to a few high cost, high volume product categories that have been included in round one of competitive bidding. The three attached charts show growth in expenditures for these items. The first chart shows growth in Medicare expenditures for wheelchairs from 1995 to 2006. This chart indicates that growth in expenditures for manual wheelchairs has been fairly modest, with total allowed charges increasing by 64 percent from $184 million in 1995 to $301 million in 2006. Medicare currently pays approximately $560 over 13 months for a standard manual wheelchair. By comparison, the growth in expenditures for power mobility devices or PMDs has been significant, with total allowed charges increasing by 1,561 percent from $59 million in 1995 to $980 million in 2006. Medicare pays approximately $4,000 in a lump sum payment for a standard power wheelchair. Just to clarify, the Medicare allowed charge data in this chart reflect expenditures for the base wheelchairs and does not include expenditures for many high cost accessories that go along with these wheelchairs, such as certain power seating systems used with power wheelchairs that are priced at approximately $9,000 a piece based on manufacturer suggested retail prices (MSRPs). In many cases, MSRP data is used to set Medicare fee schedule amounts for new technology items when the historical supplier charge data that would otherwise be used to set the fee schedule amounts are not available. The competitive bidding program offers the advantage of

allowing Medicare payment amounts to be established for these items based on supplier bids for furnishing items rather than prices set by manufacturers for their equipment.

The second chart shows the dramatic growth in expenditures for negative pressure wound therapy (NPWT) suction pumps and accessories. Medicare currently pays approximately $1,700 per month for the rental of the pump alone and expenditures for this category have grown from $30 million in 2001 to $248 million in 2006. This is another example of a fee schedule amount for a newer technology item that was established based on MSRP.

The third and final chart contains expenditure data for oxygen and oxygen equipment, the top DMEPOS category in terms of Medicare expenditures. Medicare expenditures in this category have increased from $2.2 billion in 2002 to almost $2.8 billion in 2006.

In an attempt to find an effective method for setting reasonable Medicare payments for DMEPOS and related services, the Balanced Budget Act of 1997 (BBA 1997) authorized the Secretary of Health and Human Services to conduct up to five demonstration projects to test competitive bidding. The competitive bidding demonstration for DMEPOS was implemented by CMS at two sites: Polk County, Florida and the San Antonio, Texas area.

The DMEPOS bidding demonstrations showed that competitive bidding is a viable method of establishing appropriate Medicare payments. For example:

- Costs were reduced for the Medicare Program and for beneficiaries;
- Quality of items and services was maintained; and,
- Beneficiaries kept access to needed items and services.

In the demonstration programs, the Medicare Program implemented several safeguards that assured that beneficiaries continued to have access to high quality supplies and services. One of the most important safeguards was selecting multiple winning suppliers in each category so that the beneficiaries had a choice if they were not satisfied with their supplier. An independent analysis of the project performed by RTI International found high satisfaction levels with the suppliers in the demonstration. Cost savings in the demonstration averaged 20% in the three bids

at the two locations. The demonstration design assured that small businesses could compete on a level playing field with large suppliers. Since we chose multiple winners for each product category, we were able to choose both large and small suppliers to service beneficiaries in the demonstration areas. About three-quarters of the winning bidders in the demonstration were small suppliers, defined by the Small Business Administration at the time as under $5 million in sales per year.[2]

It must also be noted that much of the observed fraud in the DMEPOS sector can be linked to high Medicare payment amounts for DMEPOS items. Since December 11, 2000, suppliers have been required to meet Medicare enrollment standards. Despite these enrollment standards, the Department of Health and Human Services, Office of Inspector General (OIG), has conducted several investigations of suppliers of DMEPOS and other items to determine the legitimacy of their businesses and has uncovered many examples of fraud and abuse. Examples of the types of fraud and abuse that were discovered include:

- Billing for items and services not performed;
- Billing for a more expensive item or service than was rendered;
- Billing separately for several items or services that should be combined into one billing;
- Billing twice for the same item or service;
- Billing for more expensive equipment or supplies than were used;
- Offering or receiving kickbacks (that is, offering or accepting something in return for services);
- Offering or accepting a bribe to use a particular service or company;
- Providing unnecessary services; and
- Submitting false cost reports.

Despite the combined resources and attention of CMS, the OIG and the Department of Justice (DOJ), the fraudulent business practices of some DMEPOS suppliers continue to cost the Medicare program millions of dollars. DMEPOS competitive bidding is expected to help

[2] Hoerger, Thomas, et al., Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report, RTI International, 2003.

address these issues, in part, by making pricing for DMEPOS and services more competitive. In addition, under the DMEPOS competitive bidding program, Medicare will only contract with suppliers that meet eligibility, financial, and quality standards and are accredited by independent accrediting organizations. This will also help deter fraud.

While the BBA-authorized demonstrations focused on the potential for more competitive pricing for DMEPOS, CMS also sustained and improved initiatives during this timeframe to address fraud and abuse activities. CMS concluded that much of the observed fraud in the DMEPOS sector can be directly tied to provider enrollment issues, and have focused its efforts to address these problems. CMS has observed that these fraudulent activities tend to concentrate in high vulnerability areas of the country such as Los Angeles, Miami and Houston where there are a large number of beneficiaries and DMEPOS providers/suppliers.

Over the last 18 months, CMS and OIG, with important input from DOJ, have identified and documented a significant amount of fraud being committed by DMEPOS suppliers in Miami and the Los Angeles metropolitan area. Both regions of the country have high numbers of Medicare beneficiaries and DMEPOS suppliers, giving rise to a heightened risk for fraud. Working with the OIG and DOJ, CMS is encouraged by the agencies' targeted initiatives in these geographic areas to protect Medicare beneficiaries from fraudulent suppliers.

MMA Reforms

The MMA mandated competitive bidding for certain DMEPOS items and services after the BBA-authorized demonstration project in Texas and Florida produced significant savings for beneficiaries and taxpayers without hindering access or quality. The MMA contained three key provisions: (1) the application of quality standards by independent accreditation organizations to ensure high quality and good customer service, (2) financial standards to ensure that contract suppliers are viable entities capable of providing consistent and high quality service to beneficiaries, and (3) competitive bidding to provide greater value to Medicare through more accurate pricing and to beneficiaries through reduced coinsurance payments. In addition, the law created the Program Advisory and Oversight Committee (PAOC). The PAOC – which has over 20 members drawn from the supplier and consumer community – has the specific role of

advising CMS during the development and implementation of DMEPOS competitive bidding. To date, the agency has held six meetings with the PAOC. More than 500 members of the public have attended these meetings.

Under the DMEPOS competitive bidding program, suppliers in a competitive bidding area will submit bids for selected DMEPOS items, and CMS will use those bids to establish Medicare payment amounts for the selected items. The purpose of the Medicare DMEPOS competitive bidding program is to harness marketplace dynamics to create incentives for suppliers to provide quality items and services in an efficient manner at a reasonable cost to Medicare beneficiaries while potentially producing significant savings for the Medicare program. Within five years of implementing the competitive bidding program, taxpayer savings are projected to exceed over $1 billion annually.

The MMA mandates that the programs be phased in so that competition occurs in 10 of the largest MSAs in 2007; 80 of the largest MSAs in 2009; and additional areas after 2009. To identify the areas with the most potential for savings, CMS selects the MSAs for purposes of competitive bidding in calendar years 2007 and 2009 by considering the following variables:

- The total population of the MSA.
- The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.
- The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.
- An MSA's geographic location.

The program provides important safeguards to ensure beneficiary access and quality, in addition to savings, as outlined below.

Quality and Accreditation Standards. The MMA required the establishment of quality standards for DMEPOS suppliers. These standards will be particularly important in ensuring that supplier quality is maintained during competitive bidding. The quality standards address suppliers' accountability, business integrity, provision of quality products to beneficiaries, and performance

management. 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.

- We conducted focus groups early in the development 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 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 solicit comments.

CMS received more than 5,600 comments on the draft quality standards. Based on these public comments, we have made significant revisions to reduce burden on small suppliers and ensure quality services for Medicare beneficiaries. The new quality standards reflect basic good business practices and certain product specific services. We expect that many suppliers already comply with the quality standards and have incorporated these practices into their daily operations.

Independent accrediting organizations will accredit suppliers that meet the quality standards. CMS has designated 10 entities as qualified to accredit DMEPOS suppliers, based on quality standards that were posted on the CMS web site in August 2006. For the first round of bidding, suppliers must have either been accredited or be pending accreditation before submitting a bid; therefore, the costs of accreditation and maintaining high quality services will be factored into suppliers' bids. All suppliers must be accredited before they are awarded a contract under the competitive bidding program

Financially viable business partners. The MMA specifies that we may not award a contract to a supplier unless that supplier meets financial standards. Evaluation of financial standards assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, financial standards for suppliers will also help maintain beneficiary access to quality services by ensuring that contract suppliers are viable entities able to consistently provide quality items and services to patients for the life of the contract. As part of the bid solicitation, each bidder submitted certain required financial documentation. CMS will evaluate each bidder's financial documentation to determine whether the supplier will be able to participate in the program and maintain viability for the duration of the contract period.

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 examples of the beneficiary protections established in the competitive bidding program:

- Competitive bidding should reduce the amount Medicare pays for DMEPOS and bring the payment amounts more in line with that of a competitive market. Also, contract suppliers must submit claims for competitive bidding items on an assignment basis. These factors will help limit the burden on beneficiaries by reducing their out-of-pocket expenses. Out-of-pocket savings for beneficiaries who use DMEPOS will come from lower coinsurance, since beneficiaries pay 20 percent of the Medicare allowed payment amount for equipment, supplies and services.

- Contract suppliers will meet the newly established DMEPOS quality standards and accreditation requirements and will follow a business model that is beneficial to beneficiaries (such as meeting financial standards). The independent accrediting organizations play a key role in ongoing monitoring of supplier quality.

- A sufficient number of contract suppliers will be selected to meet beneficiary demand.

- 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 under the competitive bidding program.

- Beneficiaries may be protected from financial liability when a non-contract supplier furnishes them with a competitively bid item.

- 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.

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

- Contract suppliers are required to make available the same range of products 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 a rented item from the same supplier (grandfathered supplier) that had been furnishing the item to the beneficiary before the implementation of a competitive bidding program, provided the supplier is willing. If a supplier agrees to furnish "grandfathered" items to one beneficiary, it must furnish those items to all.

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 needs of beneficiaries and suppliers, in particular small suppliers.

The first round of the DMEPOS competitive bidding program is currently underway. Bids have been submitted by interested suppliers and CMS is now starting the bid review process. During the implementation of this program, CMS adopted numerous strategies to protect beneficiary access to quality items and 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 $3.5 million 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 band together in "networks" in order to meet the requirement to serve the entire competitive bidding area. In addition, to help ensure that CMS has multiple suppliers, each bidder's estimated capacity, for purposes of bid evaluation only, will be limited to 20 percent of the expected beneficiary demand for a product category in a competitive bidding area (CBA). This policy will ensure multiple contract suppliers for each product category and we expect that it will result in more contract suppliers than are needed to meet demand for items and services. Most importantly, the regulation established a 30 percent target for small supplier participation in the program.

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

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.

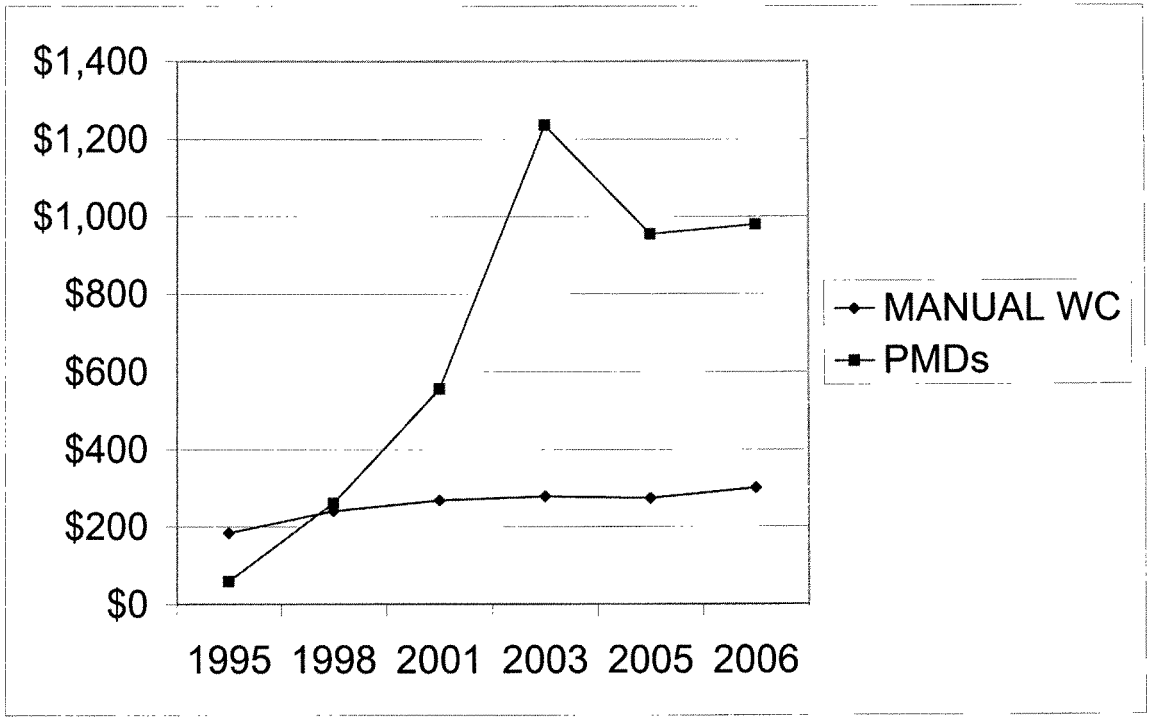
We have conducted a comprehensive education and outreach campaign to ensure that all suppliers, including small suppliers, have the information they need about the DMEPOS competitive bidding program. Preliminary education began months before the final regulation was issued, and the formal education campaign began on April 2, 2007, the day we announced the final regulation. For example, prior to opening the bidding window on May 15, 2007, we established a dedicated web site with a comprehensive array of important information, including a tool kit, fact sheets, web casts, and questions and answers. We also held Open Door Forums and sent listserv announcements to disseminate key information. After opening the bidding window, we held six bidders' conferences, during which we explained various parts of the bidding process. One of the bidders' conferences focused on small supplier issues. All of the bidders' conferences were held via teleconference to ensure maximum opportunities for suppliers to participate. We provided extensive education and support on the online bidding system. We also continued to issue answers to questions as they arose. Finally, we provided a toll-free help desk to help bidders with their issues. We believe this extensive educational campaign provided the information that potential bidders, including small suppliers, needed to submit their bids.

CMS is also aware that suppliers experienced difficulties with some aspects of CMS' implementation of the bidding process for Round I. In particular, there were intermittent technical problems with the online bidding system that presented challenges for suppliers. CMS presented these and other implementation issues to the PAOC during a meeting earlier this month in order to examine the experience from Round I with a view toward making improvements for Round II, including an enhanced online bidding system.

Conclusion

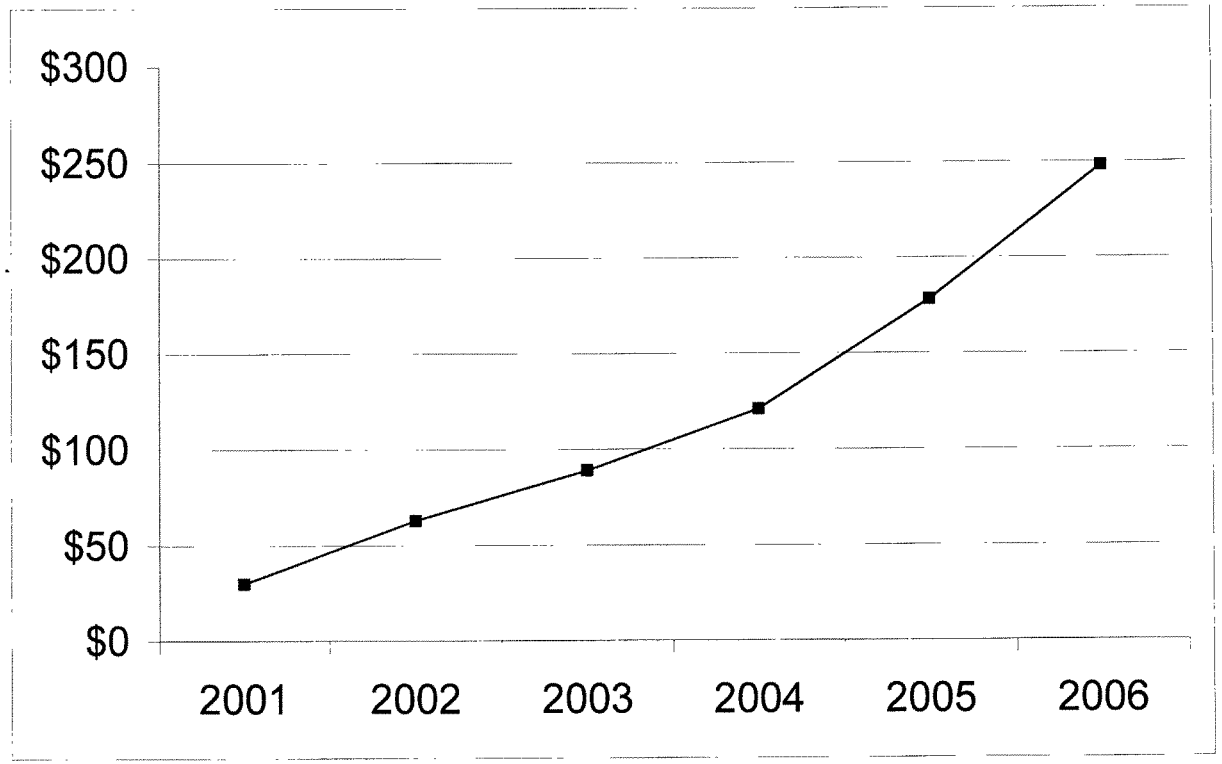
The new DMEPOS competitive bidding program is designed to bring Medicare payments to suppliers in better alignment with the competitive market. In addition, the program is an important part of the Administration's overall effort to eliminate fraudulent suppliers in Medicare and protect America's seniors. Overall, the competitive bidding program is expected to have a significant positive impact as reduced costs and improved access to higher-quality medical items and services is passed on to consumers and taxpayers with substantial savings to the Medicare program.

ATTACHMENT 1: WHEELCHAIR EXPENDITURES FROM 1995 to 2006 (Millions)*

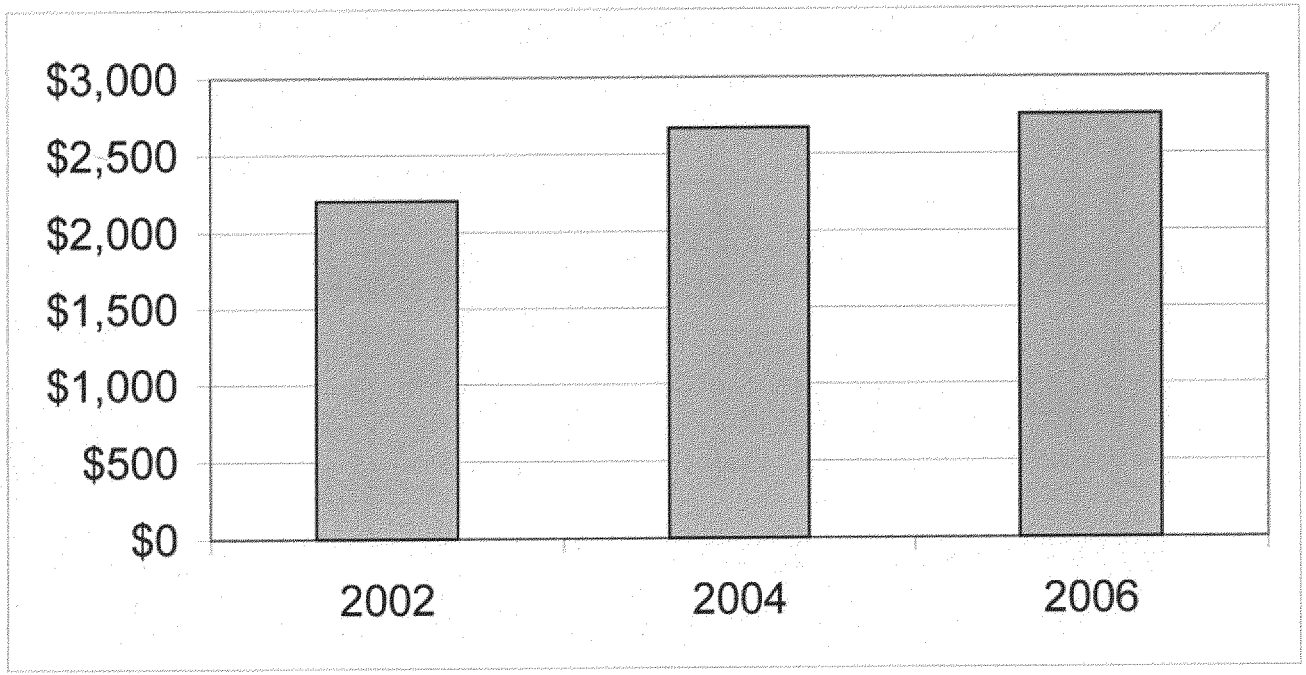


* Expenditures are for wheelchairs only and do not include expenditures for additional accessories

ATTACHMENT 2: NEGATIVE PRESSURE WOUND THERAPY (NPWT) EXPENDITURES FROM 2001 to 2006 (millions)



ATTACHMENT 3:
OXYGEN EXPENDITURES FROM 2002 to 2006 (millions)



Testimony of Dr. Ross E. Taubman

President-Elect, American Podiatric Medical Association

before the Subcommittee on Investigations and Oversight
of the House Small Business Committee

"Competitive Bidding for Durable Medical Equipment: Will Small Suppliers be able to Compete?"

October 31, 2007

Chairman Altmire, Ranking Member Gohmert, and Members of the Subcommittee, I welcome the opportunity to testify before you today on behalf of the American Podiatric Medical Association (APMA). I commend this Subcommittee for its focus on the vital issue of how competitive bidding for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) under the Medicare program will impact small businesses.

I am Dr. Ross Taubman, President Elect of the APMA and a practicing doctor of podiatric medicine. APMA is the premier professional organization representing America's Doctors of Podiatric Medicine, or "podiatrists." We represent approximately 80 percent of the podiatrists in the country, and our members provide the majority of foot care services to the Medicare population. Our mission is to advocate for the profession of podiatric medicine and surgery for the benefit of our members and the patients we serve.

Mr. Chairman, more than 60 percent of the podiatrists in this country practice in one or two person groups and would be considered small businesses. These podiatrists and practices, usually employing a very small support staff and enjoying modest annual revenues, face the same challenges confronted by all small businesses that must compete in marketplaces that are not always level playing fields. I have found during my work with APMA that many of the policy issues faced by the podiatric medical profession are, fundamentally, small business issues

that in many cases apply to other small medical practices as well. Podiatry practices and other small businesses can and do compete successfully against large businesses when the terms of that competition are fair, but success becomes difficult when arbitrary and artificial obstacles are placed in their path.

We do not believe Congress intended to construct new barriers for small businesses in recent legislation, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or "MMA," but the unintended consequences have been serious for podiatry practices. The Centers for Medicare & Medicaid Services (CMS) has proposed or issued regulations for the competitive acquisition of DMEPOS, as well as a requirement for DMEPOS suppliers to be accredited and to post a surety bond. These changes were designed to improve the quality of supplies furnished by large businesses to Medicare beneficiaries, but we believe the rules represent a genuine threat to the participation of small businesses in the Medicare program. Unfortunately, the difficulties associated with securing reimbursement for services from Medicare are among the most persistent challenges faced by podiatrists, and this burden falls disproportionately on small podiatric medical practices that cannot take advantage of economies of scale to spread the cost of regulatory compliance.

Physician Definition

One of the provisions of the MMA that authorizes the competitive acquisition program cites a restrictive definition of "physician" that includes only Medical Doctors (MDs) and Doctors of Osteopathy (DOs), but not Doctors of Podiatric Medicine (DPMs). This exclusion of podiatrists could potentially prevent them from performing the face-to-face examination required to prescribe DMEPOS for patients. (See addition to section 1834(a)(1) [42 U.S.C. 1395m(a)(1)] made by MMA Sec. 302(a)(2)(E)(ii) and (iv), attached.)

DPMs have been defined as physicians within their scope of practice in the Social Security Act Title XVIII definition under 1861(r) since 1967[1], and have both prescribed and furnished DMEPOS as part of patient care by Medicare. If taken literally and applied to the competitive bidding program, this provision could prevent patients from obtaining necessary DMEPOS, as

part of their care, from their podiatrists. For podiatric physicians, DMEPOS items such as walkers, canes, crutches, and walking boots are integral to the care we provide when a patient seeks our in-office services. A requirement that blocks this service would not just harm the bottom line of small podiatry practices by eliminating a relatively modest revenue stream from providing DMEPOS to patients, but it also would adversely affect the well-being of mobility-impaired patients who would be forced to travel elsewhere to obtain their needed medical device. Because this exclusion of podiatrists appears in the law, CMS has stated that Congress must make a technical correction to the MMA to resolve this issue.

APMA urges Congress to take such action this year as part of a broader Medicare package, and thereby ensure that podiatric physicians can continue providing DMEPOS to our elderly and disabled patients.[2]

Competitive Bidding

The DMEPOS competitive acquisition program presents specific challenges for small business medical practices. In theory, forcing suppliers of DME to competitively bid would seem like a good idea. However, in reality, this type of so-called "competitive" bidding can only be anti-competitive, leading to driving small medical practices and other small businesses out of the DMEPOS market entirely, leaving the market to a handful of large firms in each market. To understand this completely, one needs to understand how the vast majority of physicians, including podiatric physicians, utilize durable medical equipment in their offices.

Physician suppliers dispense small amounts of DME as an integral part of patient care. Consider a CAM walker, which is a specially designed "boot" typical of an item used when treating foot or ankle fractures. If a patient was seen in my office, I as a physician supplier would be able to immediately dispense this item to my patient, insuring stability of a fracture and providing immediate comfort to my patient. If subject to competitive bidding, I would need to make a bid to Medicare and be selected as a wining bidder to be able to continue to supply these items to my patients at the point of care. This is a completely unfair playing field from a cost basis. Since I may stock only two or three of a given item at a time in my small office, there is no way that I

can take advantage of economies of scale compared to a large supply house that purchases thousands of these items at a time. Therefore, it is impractical for a small business physician who dispenses DMEPOS as an integral part of patient care to compete in the competitive bidding process.

CMS made some concessions to small businesses in its final rule implementing the program but those modifications only benefit the small businesses that can submit a bid. The language intended to protect small business suppliers does not overcome the burden of producing a bid in the first place. In addition, under the final rule implementing the DMEPOS competitive bidding program, CMS did specify that physicians would be allowed to furnish certain competitively bid items to their own patients without submitting a bid and being selected as a contract supplier, as long as certain conditions were met. However, this special accommodation applies only to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and infusion pumps. It would not apply to this kind of walking boot. While most DMEPOS was not included under Phase I of the competitive bidding program (for the first 10 competitive bidding areas), if they are subjected to competitive bidding in a later phase of the program you can easily see how this would likely interfere with good patient care. For a patient with a fracture, I would almost certainly find it necessary to send him or her out of my office, perhaps across town or to another county, to get a necessary DMEPOS product from a large supply house.

Mr. Chairman, not only would this be unfair to me as a small businessman, it also would not be good medical care. In a rural area, it would be even worse and the patient in all probability would need to travel even greater distances. Therefore, I urge Congress to exempt all physician suppliers that dispense DMEPOS as an integral part of their patient care from the competitive bidding process.

Accreditation

The Medicare program's new accreditation requirements for DMEPOS suppliers also impose a burden on small medical practices (See addition to section 1834(a) (42 U.S.C. 1395m(a)) made by MMA Sec. 302(a)(1), attached.) The MMA requires all DMEPOS suppliers to be accredited

by a CMS-recognized organization. This accreditation is time-consuming, expensive, and heavy on paperwork – precisely the type of barrier that large companies are well equipped to surmount, but which pose special difficulties for small businesses that cannot afford to hire full-time regulatory compliance staff. For example, I recently downloaded the supplier manual from one of the CMS-sanctioned accrediting organizations for podiatric physicians. This 128-page manual presents the administrative red tape to meet the CMS requirements, which are unrealistic for small physician supplier practices. Additionally, the cost of accreditation essentially insures that physician suppliers will no longer be suppliers of DPMPOS for their patients. Consider that podiatrists who supply DMEPOS patients receive an average of $7,000 per year from Medicare. Accreditation costs a minimum of $3,000 per office for a three-year period. It is not difficult, therefore, to understand why we find it impractical to seek accreditation just to continue dispensing these items in our offices.

Furthermore, this sort of accreditation program is unnecessary for physicians given the comprehensive medical education and stringent licensure processes to which they are already subject. Physicians are educated in institutions of higher learning that are accredited by agencies recognized by the Department of Education. They are trained in residency programs already approved by government-recognized organizations, and they are required to meet tough state standards for licensure. To apply the same accreditation standards to physicians that supply DMEPOS as an integral part of patient care that are applied to large-scale suppliers, such as WalMart or Liberty Medical, is an unnecessary, unfair, anti-competitive and costly duplication of existing rigorous processes. Therefore, the most sound public policy would be to exempt physicians from DMEPOS supplier accreditation, and deem them accredited by reason of the substantial and more stringent licensure and accreditation requirements already required of physicians. In making this point, I think it is important to emphasize that the MMA-mandated accreditation requirements will eventually affect all DMEPOS suppliers, not just those participating in the DMEPOS competitive acquisition program.

Surety Bond

An additional DMEPOS-related burden on physician suppliers arose recently when CMS proposed to require all suppliers of DMEPOS to furnish CMS with a surety bond (CMS–6006–P Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. (72 Fed. Reg. 42001, Aug. 1, 2007). The estimated annual cost of the surety bond would be $2,000. This surety bond would not be a significant expense for a large medical supply company that does hundreds of thousands of dollars of business in DMEPOS every year. However, for small businesses, including podiatry practices, the bond requirement would provide an additional disincentive to supply DMEPOS under Medicare. This would hurt small businesses and create inconveniences for Medicare patients.

CMS has acknowledged that DMEPOS suppliers with comparatively low annual charges will have little incentive to furnish the surety bond. In fact, according to CMS, "as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities, and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented." Furthermore, CMS has indicated that DMEPOS suppliers dispensing relatively small amounts of products to Medicare beneficiaries would likely cease doing so if the proposed rule is implemented. This illustrates the danger of this proposal to small businesses, including nearly all physician suppliers of DMEPOS products, and it bears highlighting: Since the average podiatric physician generates only an average of $7,000 per year in allowed annual charges, most are almost certain to stop providing DMEPOS products under Medicare if the surety bond requirement is implemented.

I also would like to point out that Congress appears to have recognized that including physicians in surety bond requirements was bad policy when it passed the Balanced Budget Act of 1997. In that legislation and the conference report accompanying it, we believe that the Congress signaled its belief that physicians should be exempted from surety bond requirements in two ways. The Act's language notes in one place that such surety bond requirements should be applied to suppliers "other than physicians or other practitioners," while the report language states unambiguously that "the conferees wish to clarify that these surety bond requirements [plural] do not apply to physicians and other health care professionals." (See pertinent section of Conference Report for BBA97 attached.)

Given the clarity of that statutory and report language, APMA does not understand why CMS proposed to include podiatrists and other physicians in the surety bond requirement. We do not believe the intent of Congress was ambiguous, and we urge this Subcommittee and others in Congress to help make it clear to CMS that physicians should be exempted from the surety bond requirement. This proposal is particularly troubling given the likelihood that it would have a deleterious effect on Medicare beneficiaries and the small businesses that serve them.

Conclusion

Implementing rules whose predictable outcome is the exclusion of thousands of small businesses from supplying DMEPOS to Medicare beneficiaries will not help the Medicare program. According to CMS, physicians and other practitioners were responsible for only 3.1 percent of DMEPOS allowed charges in 2004, and it is unclear what, if any, program improvement would be realized by imposing these requirements on physician suppliers. In conclusion, I would like to stress that the most straightforward solution to APMA's several areas of concern with the proposed DMEPOS rules, including competitive bidding, is simply to exclude physicians from the program entirely. It is nearly impossible for physicians, including podiatric physicians, to compete against much larger businesses whose sole purpose is to supply medical equipment as opposed to providing patient care.

Mr. Chairman and Members of the Subcommittee, I again thank you for providing me with the opportunity to speak today on behalf of the APMA and podiatric physicians regarding the challenges presented by Medicare's competitive bidding program, supplier accreditation, and the proposed surety bonds for DMEPOS suppliers. Attached to my written testimony are comments that we have submitted to CMS and other background documents. I respectfully submit these letters to the subcommittee and ask that they be included in the record. I will be happy to answer any questions you may have.

[1] Sec. 1861. [42 U.S.C. 1395x] Part E—Miscellaneous Provisions
DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.
(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

[2] Proposed amendment to the Social Security Act (as amended by the MMA) to correct the Physician Definition cited and ensure Medicare patient access to DMEPOS:
(a) Section 1834(a)(1)(E)(ii) of the Social Security Act is amended by striking "(1)" from "section 1861(r)(1)"
(b) Section 1834(a)(1)(E)(iv) of the Social Security Act is amended by striking "(1)" from "section 1861(r)(1)"

H.R.1

One Hundred Eighth Congress
of the
United States of America
AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday,

the seventh day of January, two thousand and three

An Act

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIPMENT; COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) QUALITY ENHANCEMENT AND FRAUD REDUCTION-
(1) ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT SUPPLIERS- Section 1834(a) (42 U.S.C. 1395m(a)) is amended--
(A) by transferring paragraph (17), as added by section 4551(c)(1) of the Balanced Budget Act of 1997 (111 Stat. 458), to the end of such section and redesignating such paragraph as paragraph (19); and
(B) by adding at the end the following new paragraph:
`(20) IDENTIFICATION OF QUALITY STANDARDS-
`(A) IN GENERAL- Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations

(as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to--

`(i) furnish any such item or service for which payment is made under this part; and

`(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

`(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS- Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(b), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

`(C) QUALITY STANDARDS- The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

`(D) ITEMS AND SERVICES DESCRIBED- The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

`(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

`(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

`(iii) Items and services described in section 1842(s)(2).

`(E) IMPLEMENTATION- The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.'.

(2) ESTABLISHMENT OF CLINICAL CONDITIONS OF COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL EQUIPMENT- Section 1834(a)(1) (42 U.S.C.

1395m(a)(1)) is amended by adding at the end the following new subparagraph:

`(E) CLINICAL CONDITIONS FOR COVERAGE-

`(i) IN GENERAL- The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

`(ii) REQUIREMENTS- The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

`(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS- In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

`(iv) STANDARDS FOR POWER WHEELCHAIRS- Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

`(v) LIMITATION ON PAYMENT FOR COVERED ITEMS- Payment may not be made for a covered item under this subsection unless the item meets any standards established under

this subparagraph for clinical condition of coverage.'.

(b) COMPETITIVE ACQUISITION-

(1) IN GENERAL- Section 1847 (42 U.S.C. 1395w-3) is amended to read as follows:

`COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

`SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS-

`(1) IMPLEMENTATION OF PROGRAMS-

`(A) IN GENERAL- The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

`(B) PHASED-IN IMPLEMENTATION- The programs--

`(i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in--

`(I) 10 of the largest metropolitan statistical areas in 2007;

`(II) 80 of the largest metropolitan statistical areas in 2009; and

`(III) additional areas after 2009; and

`(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

`(C) WAIVER OF CERTAIN PROVISIONS- In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

`(2) ITEMS AND SERVICES DESCRIBED- The items and services referred to in paragraph (1) are the following:

`(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES- Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

`(B) OTHER EQUIPMENT AND SUPPLIES- Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

`(C) OFF-THE-SHELF ORTHOTICS- Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

`(3) EXCEPTION AUTHORITY- In carrying out the programs under this section, the Secretary may exempt--

`(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

`(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

`(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT AND OXYGEN- In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

`(5) PHYSICIAN AUTHORIZATION-

`(A) IN GENERAL- With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items

and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

`(B) NO EFFECT ON PAYMENT AMOUNT- A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

`(6) APPLICATION- For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s), as appropriate.

`(b) PROGRAM REQUIREMENTS-

`(1) IN GENERAL- The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

`(2) CONDITIONS FOR AWARDING CONTRACT-

`(A) IN GENERAL- The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

`(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

`(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

`(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

`(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

`(B) TIMELY IMPLEMENTATION OF PROGRAM- Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

`(3) CONTENTS OF CONTRACT-

`(A) IN GENERAL- A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

`(B) TERM OF CONTRACTS- The Secretary shall recompete contracts under this section not less often than once every 3 years.

`(4) LIMIT ON NUMBER OF CONTRACTORS-

`(A) IN GENERAL- The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

`(B) MULTIPLE WINNERS- The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

`(5) PAYMENT-

`(A) IN GENERAL- Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

`(B) REDUCED BENEFICIARY COST-SHARING-

`(i) APPLICATION OF COINSURANCE- Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

`(ii) APPLICATION OF DEDUCTIBLE- Before applying clause (i), the individual shall be

required to meet the deductible described in section 1833(b).

`(C) PAYMENT ON ASSIGNMENT-RELATED BASIS- Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

`(D) CONSTRUCTION- Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

`(6) PARTICIPATING CONTRACTORS-

`(A) IN GENERAL- Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless--

`(i) the contractor has submitted a bid for such items and services under this section; and

`(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

`(B) BID DEFINED- In this section, the term `bid' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

`(C) RULES FOR MERGERS AND ACQUISITIONS- In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

`(D) PROTECTION OF SMALL SUPPLIERS- In developing procedures relating to bids and the awarding of contracts under this section, 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 under this section.

`(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS- The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

`(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES- The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

`(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION- The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

`(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW- There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of--

`(A) the establishment of payment amounts under paragraph (5);

`(B) the awarding of contracts under this section;

`(C) the designation of competitive acquisition areas under subsection (a)(1)(A);

`(D) the phased-in implementation under subsection (a)(1)(B);

`(E) the selection of items and services for competitive acquisition under subsection (a)(2); or

`(F) the bidding structure and number of contractors selected under this section.

`(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE-

`(1) ESTABLISHMENT- The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the `Committee').

`(2) MEMBERSHIP; TERMS- The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

`(3) DUTIES-

`(A) ADVICE- The Committee shall provide advice to the Secretary with respect to the following functions:

`(i) The implementation of the program under this section.

`(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

`(iii) The establishment of requirements for collection of data for the efficient management of the program.

`(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.

`(v) The establishment of quality standards under section 1834(a)(20).

`(B) ADDITIONAL DUTIES- The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

`(4) INAPPLICABILITY OF FACA- The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

`(5) TERMINATION- The Committee shall terminate on December 31, 2009.

`(d) REPORT- Not later than July 1, 2009, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

`(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES-

`(1) IN GENERAL- The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests--

`(A) for which payment would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1834(d)(1) (relating to colorectal cancer screening tests); and

`(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

`(2) TERMS AND CONDITIONS-

`(A) IN GENERAL- Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

`(B) APPLICATION OF CLIA QUALITY STANDARDS- The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such

tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

`(3) REPORT- The Secretary shall submit to Congress--

`(A) an initial report on the project not later than December 31, 2005; and

`(B) such progress and final reports on the project after such date as the Secretary determines appropriate.'.

(2) CONFORMING AMENDMENTS- Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended--

(A) by striking `and (U)' and inserting `(U)';

(B) by inserting before the semicolon at the end the following: `, and (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5)'; and

(C) in clause (D)--

(i) by striking `or (ii)' and inserting `(ii)'; and

(ii) by adding at the end the following: `or (iii) on the basis of a rate established under a demonstration project under section 1847(e), the amount paid shall be equal to 100 percent of such rate,'.

(3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION ON SUPPLIERS-

(A) STUDY- The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act, as amended by paragraph (1), on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment.

(B) REPORT- Not later than January 1, 2009, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph

(A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

(c) TRANSITIONAL FREEZE-

(1) DME-

(A) IN GENERAL- Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended--

(i) in subparagraph (E), by striking `and' at the end;

(ii) in subparagraph (F)--

(I) by striking `a subsequent year' and inserting `2003'; and

(II) by striking `the previous year.' and inserting `2002;'; and

(iii) by adding at the end the following new subparagraphs:

`(G) for 2004 through 2006--

`(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

`(ii) in the case of covered items not described in clause (i), 0 percentage points;

`(H) for 2007--

`(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

`(ii) in the case of covered items not described in clause (i), 0 percentage points; and

`(I) for 2008--

`(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the

percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

`(ii) in the case of covered items not described in clause (i), 0 percentage points; and

`(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.'.

(B) GAO REPORT ON CLASS III MEDICAL DEVICES- Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary, a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) furnished to medicare beneficiaries during 2007 and 2008.

(2) PAYMENT RULE FOR SPECIFIED ITEMS- Section 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

`(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES-

`(A) IN GENERAL- Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between--

`(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

`(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled `Median FEHP Price' in the table entitled `SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND

FEHP PRICES FOR 16 ITEMS' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

`(B) SPECIFIED ITEM OR SUPPLY DESCRIBED- For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

`(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT- The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.'.

(3) PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS- Section 1834(h)(4)(A) (42 U.S.C. 1395m(h)(4)(A)) is amended--

(A) in clause (vii), by striking `and' at the end;

(B) in clause (viii), by striking `a subsequent year' and inserting `2003'; and

(C) by adding at the end the following new clauses:

`(ix) for 2004, 2005, and 2006, 0 percent; and

`(x) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;'.

(d) CONFORMING AMENDMENTS-

(1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- Section 1834(a) (42 U.S.C. 1395m(a)) is amended--

(A) in paragraph (1)(B), by striking `The payment basis' and inserting `Subject to subparagraph (F)(i), the payment basis';

(B) in paragraph (1)(C), by striking `This subsection' and inserting `Subject to subparagraph (F)(ii), this subsection';

(C) by adding at the end of paragraph (1) the following new subparagraph:

`(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- In the case of covered items furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)--

`(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

`(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.'; and

(D) in paragraph (10)(B), by inserting `in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F)' after `under this subsection'.

(2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- Section 1834(h) (42 U.S.C. 1395m(h)) is amended--

(A) in paragraph (1)(B), by striking `and (E)' and inserting `, (E), and (H)(i)';

(B) in paragraph (1)(D), by striking `This subsection' and inserting `Subject to subparagraph (H)(ii), this subsection'; and

(C) by adding at the end of paragraph (1) the following new subparagraph:

`(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under such section--

`(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

`(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.'.

(3) OTHER ITEMS AND SERVICES; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- Section 1842(s) (42 U.S.C. 1395u(s)) is amended--

(A) in the first sentence of paragraph (1), by striking `The Secretary' and inserting `Subject to paragraph (3), the Secretary'; and

(B) by adding at the end the following new paragraph:

`(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)--

`(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

`(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.'.

(e) REPORT ON ACTIVITIES OF SUPPLIERS- The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than

July 1, 2009, the Inspector General shall submit to Congress a report on such study.

SEC. 4312. DISCLOSURE OF INFORMATION AND SURETY BONDS.

(a) DISCLOSURE OF INFORMATION AND SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT- Section 1834(a) (42 U.S.C. 1395m(a)) is amended by inserting after paragraph (15) the following new paragraph:

`(16) DISCLOSURE OF INFORMATION AND SURETY BOND- The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis--

`(A) with--

`(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

`(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

`(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law.'.

(b) SURETY BOND REQUIREMENT FOR HOME HEALTH AGENCIES-

(1) IN GENERAL- Section 1861(o) (42 U.S.C. 1395x(o)) is amended--

(A) in paragraph (6), by striking `and' at the end;

(B) by redesignating paragraph (7) as paragraph (8);

(C) by inserting after paragraph (6) the following new paragraph:

`(7) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and'; and

(D) by adding at the end the following: `The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.'.

(2) CONFORMING AMENDMENTS- Section 1861(v)(1)(H) (42 U.S.C. 1395x(v)(1)(H)) is amended--

(A) in clause (i), by striking `the financial security requirement described in subsection (o)(7)' and inserting `the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8)'; and

(B) in clause (ii), by striking `the financial security requirement described in subsection (o)(7) applies' and inserting `the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply'.

(3) REFERENCE TO CURRENT DISCLOSURE REQUIREMENT- For additional provisions requiring home health agencies to disclose information on ownership and control interests, see section 1124 of the Social Security Act (42 U.S.C. 1320a-3).

(c) AUTHORIZING APPLICATION OF DISCLOSURE AND SURETY BOND REQUIREMENTS TO OTHER HEALTH CARE PROVIDERS- Section 1834(a)(16) (42 U.S.C. 1395m(a)(16)), as added by subsection (a), is amended by adding at the end the following: `The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C)) who furnish items or services under this part.'.

(d) APPLICATION TO COMPREHENSIVE OUTPATIENT REHABILITATION FACILITIES (CORFS)- Section 1861(cc)(2) (42 U.S.C. 1395x(cc)(2)) is amended--

(1) in subparagraph (H), by striking `and' at the end;

(2) by redesignating subparagraph (I) as subparagraph (J);

(3) by inserting after subparagraph (H) the following new subparagraph:

`(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and'; and

(4) by adding at the end the following flush sentence:

`The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.'.

(e) APPLICATION TO REHABILITATION AGENCIES- Section 1861(p) (42 U.S.C. 1395x(p)) is amended--

(1) in paragraph (4)(A)(v), by inserting after `as the Secretary may find necessary,' the following: `and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000,', and

(2) by adding at the end the following: `The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.'.

(f) EFFECTIVE DATES-

(1) SUPPLIERS OF DURABLE MEDICAL EQUIPMENT- The amendment made by subsection (a) shall apply to suppliers of durable medical equipment with respect to such equipment furnished on or after January 1, 1998.

(2) HOME HEALTH AGENCIES- The amendments made by subsection (b) shall apply to home health agencies with respect to services furnished on or after January 1, 1998. The Secretary of Health and Human Services shall modify participation agreements under section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)) with respect to home health agencies to provide for implementation of such amendments on a timely basis.

(3) OTHER AMENDMENTS- The amendments made by subsections (c) through (e) shall take effect on the date of the enactment of this Act and may be applied with respect to items and services furnished on or after January 1, 1998.

105TH CONGRESS
1st Session
REPORT 105–217

BALANCED BUDGET ACT OF 1997
CONFERENCE REPORT

TO ACCOMPANY

H.R. 2015

JULY 30, (legislative day of JULY 29), 1997.—Ordered to be printed

DISCLOSURE OF INFORMATION AND SURETY BONDS

Section 10307 and 4307 of House bill and Section 5211 of Senate Amendment

CURRENT LAW

Section 1834(a) of the Social Security Act establishes requirements for payments under Medicare for covered items defined as durable medical equipment. Home health agencies are required, under Section 1861(o) of the Social Security Act, to meet specified conditions in order to provide health care services under Medicare, including requirements, set by the Secretary, relating to bonding or establishing of escrow accounts, as the Secretary finds necessary for the effective and efficient operation of the Medicare program.

HOUSE BILL

Section 10307. Requires that suppliers of durable medical equipment provide the Secretary with full and complete information as to persons with an ownership or control interest in the supplier, or in any subcontractor in which the supplier has a direct or indirect 5 percent or more ownership interest, other information concerning such ownership or control, and a surety bond for at least $50,000. Home health agencies, comprehensive outpatient rehabilitation facilities, and rehabilitation agencies would also be required to provide a surety bond for at least $50,000. The Secretary may impose the surety bond requirement which applies to durable medical equipment suppliers to suppliers of ambulance services and certain clinics that furnish medical and other health services (other than physicians' services). In each of these cases the Secretary could waive the surety bond requirement if the entity provides a comparable surety bond under state law.

Section 4307. Identical provision.

Effective Date. Applies with respect to items and services furnished on or after January 1, 1998.

SENATE AMENDMENT

Identical, except minor wording differences and provision that Secretary may also require a supplier of durable medical equipment to provide evidence of compliance with applicable Medicare conditions or requirements through an accreditation survey conducted by a national accreditation body.

CONFERENCE AGREEMENT

The conference agreement includes provisions in the House bill and the Senate amendment which are similar, with a modification making all surety bond requirements mandatory and eliminating the Senate amendment language regarding accreditation, and with clarifying language.

The Conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals.

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

June 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1270-P: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654, May 1, 2006

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier podiatric physicians and surgeons, is pleased to present comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule, *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. The proposed rule would implement competitive bidding programs for certain covered items of DMEPOS. We believe that as proposed, the new program has the potential to interfere with patient care and will harm Medicare beneficiaries. We urge CMS to revise its proposals prior to implementation of a new competitive bidding program.

We would like to take this opportunity to express appreciation to your staff from the Chronic Care Policy Group and Division of Community Post Acute Care, who met with us on June 21 to discuss provisions of the proposed rule in greater detail. That meeting assisted us in clarifying specific issues of concern and we offer the following comments:

Submission of Bids under the Competitive Bidding Program

The proposed rule specifies that "physicians" that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items subject to competitive bidding in an area. It also notes that "physicians" that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients. Further, the proposed rule states that "physicians" will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. In other words, such "physicians" would not be required to serve an entire competitive bidding area. Finally, the proposed rule has chosen to define the term "physician" by reference to 1861(r)(1) of the Social Security Act (which covers only doctors of medicine and doctors of osteopathy), rather than the more typical reference to 1861(r), which would also include doctors of

podiatric medicine. Below we outline in considerable detail our concerns about these aspects of the proposed rule. We begin by describing how podiatric physicians use certain DMEPOS products as an integral part of the services they provide to their patients, and how the new competitive bidding program could interfere with the practice of podiatric medicine.

DMEPOS Use by Podiatric Physicians

As podiatric physicians and surgeons, our members prescribe and supply DMEPOS items as an integral part of patient care. Similar to medical doctors (MDs) and doctors of osteopathy (DOs), our members are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. Our members are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy all other Federal and State regulatory requirements.

According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Our members provide medically necessary and appropriate DMEPOS items in treating Medicare beneficiaries. Examples of how podiatric physicians utilize DMEPOS in patient care include:

A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

Or, the podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier in the new competitive acquisition program because he or she was unsuccessful in competing to bid to supply to the entire Metropolitan Statistical Area (MSA) rather than just to his patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities.

If the patient is unable to acquire the item from the treating physician and must instead obtain the item from another supplier due to the new competitive acquisition program, negative consequences could

result. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient.

For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

For non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination.

If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

Exclude All Physicians and Qualified Healthcare Practitioners From the DMEPOS Competitive Bidding Program

The APMA believes that all physicians, including podiatric physicians, as well as other qualified healthcare practitioners who utilize DMEPOS when caring for Medicare beneficiaries, should be exempted from the requirement to competitively bid to supply DMEPOS to their own patients. According to 2004 data on DMEPOS services, practitioners were responsible for 3.1% of DMEPOS allowed charges as a percent of all allowed charges while entities categorized as "suppliers" were responsible for 96.4% of those charges. Clearly, there is a vast difference in the amount of DMEPOS supplied by physicians and other practitioners compared to that supplied by traditional suppliers.

Most of our physicians supply limited quantities of DMEPOS items to Medicare beneficiaries. They do not maintain significant inventories and sometimes may have only one or two of a particular type of item available in the office. As an item is used, it is replenished. We seriously question the ability of our members or other physician or practitioner suppliers to compete against entities with the ability to purchase vast quantities of products in bulk. If individuals believe that competing against these larger entities is hopeless, many will not even try. If CMS expects physicians and other qualified practitioners to be able to successfully bid to supply items for the future, it needs to provide more details on the selection process; otherwise, individuals will be deterred from bidding before the program even starts.

Physicians and other practitioners who operate as small businesses and whose primary mission is to provide quality patient care that is medically necessary and appropriate and who use DMEPOS solely for purposes of enhancing that care will face significant administrative and financial burdens in trying to compete in this new program. To the detriment of patient care, many will decide against submitting a bid and will be excluded as suppliers. Rather than disrupt Medicare beneficiary access to care that is in their best interest and that occurs at a single point-of-service, we urge CMS to exclude all physicians recognized by Medicare, as well as other qualified healthcare practitioners from the requirement to competitively bid.

It is clear to the APMA that any financial gains made as a result of the proposed rule would be minimal whereas the potential risks to patient health would be huge. We fail to understand the logic of this proposal that would prevent doctors of podiatric medicine (DPMs) from being defined as physicians. We also are convinced that while the competitive bidding process may save the program some money in the initial phase, it will not only cost more to care for the complications of delayed and inappropriate care but will harm the patients we are committed to serve.

Exempt Items Integral to Patient Care

If CMS is uncertain whether the current statute would permit the agency to exclude physicians from competitive bidding altogether, as we recommend, we believe there is another alternative, at least during the early rounds of competitive bidding. CMS could exempt from competitive bidding items that are used as an integral part of patient care provided by physicians and other qualified healthcare practitioners. This would not only allow physicians to continue to serve their Medicare patients without undue interference, it would also provide time for CMS to consult with relevant Congressional Committees regarding the current statutory language and the possible need for amendments or clarifications.

In broad terms, we suggest that the following product categories be excluded from competitive bidding: diabetic shoes, diabetic inlays, prosthetics for the foot, and diabetic adjustments; fractures/sprain/injury related items, such as crutches, pneumatic walkers, other fracture ankle-foot orthoses (AFOs), items for ankle injuries, including braces and splints, and plantar fascia splints; AFOs, including non-pneumatic

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walkers; and select wound care products, including negative pressure wound therapy (NPWT). If CMS prefers a more detailed list of suggested products for exclusion, we will be happy to comply. We are prepared to suggest items by HCPCS code if necessary and request that CMS contact us if more specific recommendations are required.

As we understand it, CMS believes that Therapeutic Shoes for Individuals with Diabetes (TSD) items are not subject to competitive bidding, although this is not specifically mentioned in the proposed rule. APMA strongly supports such exclusion. These items are provided for patients identified as being at risk and ensuring proper fit of TSD items is essential. If items are not fitted and used properly, complications could occur that might result in loss of limb or life. Since specific existing regulations apply regarding the certification of need, prescription and dispensing of those items, we believe that including them in competitive bidding would be counter-productive to patient care.

Additionally, we note that the proposed rule mentions in passing (in the impact analysis) that surgical dressings are not eligible for competitive bidding, and we support such exclusion as well. Many of the surgical dressings are used in wound care and must be available to patients undergoing treatment for acute or chronic wounds.

Specifically in relationship to the treatment of wounds, we believe that physician choice when determining appropriate wound care products is of paramount importance. Our members treat a wide variety of wounds, including diabetic ulcers. Our members save life and limb and contribute to the improvement of the quality of life and duration of life for Medicare beneficiaries, especially those with diabetes. There are a variety of challenges in providing wound care, not the least of which is that proper care can be costly, involve pain and suffering for patients, and interfere with the patient's activities of daily living and other normal activities.

We are concerned that physician choice and access to certain wound care products could be restricted as a result of the new competitive bidding process. An item of particular concern for our members is negative pressure wound therapy. In October 2000, a new HCPCS code, E2402, was established for NPWT and since 2003 more than 3,000 physicians have ordered NPWT more than 36,000 times.

In recent months, new products have been added to the E2402 code despite the fact that these new products are clinically different from the original NPWT product. Case studies involving the original NPWT product are attached for your review. As demonstrated, these products are used for wounds that are significant. In one of the case studies, the product is used post-amputation and after eight weeks of use, wound healing is evident. If this product were no longer available because only newer items described by HCPCS code E2402 are provided by contract suppliers, it is conceivable that wound healing could be compromised.

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Since the category described by E2402 includes newer items that are not yet well understood or established and physician choice in selecting an item must be respected, we suggest that it is too risky to competitively bid that category at this time. Therefore, we recommend that NPWT products are not among those subject to the initial round of competitive bidding.

Finally, we note that, as mandated by the MMA, the proposed rule calls for subjecting only off-the-shelf orthotics (and not custom-made orthotics) to competitive bidding. APMA strongly supports the Congressional decision to exclude custom-made orthotics from the list of products eligible for competitive bidding.

Allow Physicians to Continue as Suppliers at the MSA Rate

Another option CMS could consider is to allow physicians and other qualified healthcare practitioners to continue to supply DMEPOS as they currently do provided they agree to supply the item at the single payment amount, the same rate that applies to the entire MSA. Since the proposed rule suggests establishing a single rate for each product subject to bidding in each MSA, the "bid" of the physician or other qualified healthcare practitioner would simply be a statement confirming their willingness to serve as a supplier and to supply items at the rate established by CMS. For physician-suppliers, we believe that such a bid could still be viewed as satisfying the statutory requirement that a bid specify "a particular price." In addition, since all or nearly all physician-suppliers are likely to easily satisfy any definition of "small supplier," our recommended approach for handling bids from physician-suppliers would help CMS respond to the statutory requirement that the Secretary "take appropriate steps to ensure that small suppliers...have the opportunity to be considered for participation in the [DMEPOS competitive acquisition] program."

This option would ensure that Medicare beneficiaries' access to patient care and to medically necessary and appropriate items is not negatively impacted as a result of the new program. They could continue to receive items from their physician or other qualified healthcare professional while still allowing CMS to achieve cost savings since the item would be provided at the CMS rate.

Physician Definition Should be Changed to 1861(r)

Based upon our June 21 meeting with CMS representatives, we understand that it is the agency's position that the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)* requires CMS to establish a competitive bidding program for all suppliers of DMEPOS. While we continue to believe that physicians and other qualified practitioners should be exempted from the requirement to competitively bid, it appears that CMS will proceed with competitive bidding for all suppliers. There are provisions within the proposed rule that will negatively impact a podiatric physician's ability to supply

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medically necessary and appropriate DMEPOS to Medicare beneficiaries as an integral part of patient care.

The proposed definition of "physician" could lead some to conclude that podiatric physicians would not be allowed to participate in the new DMEPOS competitive bidding program. However, as we understand it, that was **not** CMS' intent. As noted earlier, more than 7,300 podiatric physicians currently have DMEPOS supplier numbers, and thus it seems rather doubtful that Congress would have intended to bar these individuals from continuing to serve as suppliers. In any case, the proposed definition of "physician" would appear to have other negative consequences for podiatric physicians and their patients. Since CMS did not recognize podiatrists as physicians for purposes of the proposed rule, podiatric physicians will not be able to bid to supply DMEPOS items to their patients only. Additionally, podiatric physicians will not have the ability to execute a physician authorization when they determine that a particular brand of item is necessary for the patient. We believe this decision will have serious consequences for our members and the Medicare beneficiaries they serve.

As noted earlier, in the proposed rule, CMS defined physician using the narrow 1861(r)(1) definition, which applies to MDs and DOs only. Since the prescribing, fabricating, fitting and dispensing of DMEPOS is within our scope of practice as defined by state law, this proposed action is in direct conflict with those laws as written.

We question why CMS selected this definition when our members provide DMEPOS items the same way that they are provided by MD and DO physicians. Our members perform a thorough evaluation of the patient prior to determining a course of treatment. As stated previously, our members prescribe and supply DMEPOS items as an integral part of patient care. They are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. They are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy other Federal and State regulatory requirements. If a DMEPOS item is necessary, our members prescribe the item and if they have a valid supplier number, they may dispense that item in their office. Therefore, we urge CMS to revise the physician definition to 1861(r) so that all physicians recognized by Medicare are able to bid to supply items to their patients only and are able to execute a physician authorization. Additionally, we believe that other qualified healthcare practitioners should be able to supply DMEPOS that is used as an integral part of patient care.

We see nothing in the MMA that requires the proposed, narrow definition of "physician" for purposes of the DMEPOS competitive bidding program. We recognize that a separate provision, relating to the need for a face-to-face examination of a patient for coverage of certain DMEPOS, does limit the definition of physician to 1861(r)(1), but this provision is currently being applied only to power mobility devices and does not directly relate to the competitive bidding program.

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In sum, we urge CMS to modify the definition used for physicians who may bid to supply DMEPOS to their patients only and who may execute a physician authorization from 1861(r)(1) to 1861(r).

Criteria for Item Selection

We realize that CMS has yet to identify the specific products or product categories that will initially be subject to bidding. We suggest that care be exercised in establishing the product categories for the future. Scope of practice limitations exist for our members and it would not make sense to require podiatric physicians to, for example, competitively bid to supply all off-the-shelf orthotics. Our members supply lower extremity orthotics and would be unable to supply upper extremity orthotics. Other specialties could be similarly challenged. For instance, it is unlikely that orthopedic hand surgeons would supply lower extremity orthotics. When establishing product categories, we urge CMS to be realistic and avoid making the categories so broad that it actually prevents some specialties from bidding.

Quality Standards and Accreditation for Suppliers of DMEPOS

The APMA is concerned with the application of quality standards, as well as the establishment of an accreditation process, for all suppliers of DMEPOS. Specifically, if a uniform set of standards and a single accreditation process are utilized, it is conceivable that the standards and process could be so onerous or expensive that physician suppliers would be unable or unwilling to serve as DMEPOS suppliers. As a result, patient care could suffer.

While we recognize that the proposed rule was limited in its discussion of the quality standards and accreditation process, and we expect the release of the final quality standards in the near future, we believe physicians should have a unique set of quality standards and a separate accreditation process. At the very least, we object to a uniform set of standards and a single accreditation process for all suppliers of DMEPOS. We believe that the standards and accreditation process should be fair and reasonable and should be reflective of the amount of DMEPOS supplied to Medicare beneficiaries.

Podiatric and other physicians must obviously meet state licensing requirements, and subjecting them to additional or potentially duplicative requirements could be overly and unnecessarily burdensome. We believe that it is reasonable to utilize a process for physician suppliers that differs from the one used for traditional suppliers lacking professional licensure. To subject a licensed physician, who might supply $5,000 worth of DMEPOS to Medicare beneficiaries over the course of a year to the same standards and accreditation process that apply to an entity supplying $1,000,000 worth of DMEPOS seems unreasonable. We encourage CMS to be reasonable in establishing quality standards and an accreditation process for physician suppliers.

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Additionally, if the costs associated with becoming accredited (including the fee paid to the accreditation organization) are excessive when compared to the amount of DMEPOS supplied, or the process is overly burdensome, physicians may decide against functioning as DMEPOS suppliers. Patient access and patient care could be compromised.

If accreditation is required for all suppliers, physicians must have equal and appropriate access to the accrediting organizations. A single accrediting body for podiatric physicians who supply DMEPOS does not exist. Since accreditation by suppliers will be required before the program starts, our members would be disadvantaged. Other physicians and qualified healthcare practitioners would likely face similar challenges. We believe that if CMS intends to require an accreditation process for physicians beyond state licensing, the agency must ensure that a reasonable and fair pathway exists for physicians and other qualified healthcare professionals who wish to become accredited. The details of the accreditation process should be immediately communicated so that physicians and other qualified healthcare practitioners who wish to serve as suppliers in the new competitive bidding program understand the process they must follow.

Conclusion

The APMA appreciates the opportunity to offer these comments. The competitive bidding program, as proposed, is of significant concern to our members and we are hopeful that CMS will revise its proposals prior to issuing final regulations. If you have questions or require additional details, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

David M. Schofield, DPM
President

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September 28, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–6006–P
P.O. Box 8017, Baltimore, MD 21244–8017.

RE: CMS–6006–P
Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
(72 Fed. Reg. 42001, Aug. 1, 2007)

Comments submitted electronically at http://www.cms.hhs.gov/eRulemaking

Dear Mr. Weems:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier foot and ankle physicians and surgeons, is pleased to comment on the proposed rule that would require Medicare suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to obtain a surety bond.

PROVISIONS

The proposed rule would require all DMEPOS suppliers to obtain a surety bond. However, the Centers for Medicare & Medicaid Services (CMS) invited comments on the need for exemptions for various types of suppliers, including physicians and non-physician practitioners. The APMA believes very strongly that any surety bond requirement should not apply to physicians, including podiatric physicians, even in their role as DMEPOS suppliers. We have two compelling reasons physicians (defined in Section 1861(r) of the Social Security Act) should be exempt.

First, the APMA believes that the Congress did not intend surety bond requirements to apply to physicians, including podiatric physicians. We note, for example, that the conference report language accompanying the Balanced Budget Act of 1997 (BBA) includes the following expression of Congressional intent:

> "The conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals" [emphasis added].

Please note that the above excerpt from the conference report explicitly refers to surety bond requirements in the plural, which we believe is an indication that the Congress did not intend any of the surety bond requirements specified in section 4312 of the BBA to apply to physicians or non-physician practitioners. In addition to looking at the conference report, we believe that Congressional intent can be found in the statute itself. Section 4312(c) of the BBA, which provides authority for the Secretary to apply surety bond requirements to health care providers other than

suppliers of durable medical equipment, explicitly states that any such extension may not apply to "physicians or other practitioners, as defined in section 1842(b)(18)(C)..." We assume that it is this specific section of the BBA that is being relied upon by CMS in proposing surety bond requirements for suppliers of prosthetics, prosthetic devices, and orthotics. In making this assumption, we note that section 4312(a) of the BBA only refers to suppliers of durable medical equipment, not prosthetics, prosthetic devices or orthotics. In the past, the Congress has been explicit when it wished specific requirements to apply to all suppliers of DMEPOS, not just suppliers of durable medical equipment. For example, when Congress mandated new quality standards for DMEPOS suppliers (at section 1834(a)(20) of the Social Security Act), it explicitly enumerated the items and services to be covered by such standards to include not only durable medical equipment, but "prosthetic devices and orthotics and prosthetics." Moreover, we assume that specific reference to the phrase "excluding physician and other practitioners as defined in section 1842(b)(18)(C) of the Act" in the impact analysis accompanying the proposed rule (see page 42008 of the August 1, 2007 *Federal Register*, first column bottom) is an allusion to the language in section 4312(c) of the BBA, suggesting CMS recognition that the Congress had expressed a view with respect to the exemption of such practitioners from surety bond requirements.

Taken together, then, we believe that the conference report and statutory excerpts mentioned above provide considerable evidence that the Congress intended to exempt physicians, including podiatric physicians, from any surety bond requirements. We note, too, that there appears to be no similar expression of Congressional intent, vague or otherwise, with respect to large publicly traded suppliers, rural DMEPOS suppliers or the other categories of suppliers for which CMS has invited comments about possible exemptions.

Second, and more important than any legal consideration, the APMA believes that the application of surety bond requirements to physicians and other practitioners will seriously compromise Medicare beneficiary access to high quality care. In the case of physicians, including podiatric physicians, DMEPOS products are provided as an integral part of patient care. Further, in the case of physicians, DMEPOS products typically make up only a relatively small proportion of the total items and services routinely provided to Medicare beneficiaries. CMS itself projects that the proposed surety bond requirements will cause many if not all DMEPOS suppliers who now provide relatively small quantities of DMEPOS to Medicare beneficiaries to cease doing so, and the APMA believes that many such suppliers will be physicians. As noted by CMS in the proposed rule, physicians, including podiatric physicians, cannot incur the cost of a surety bond if there is little or no likelihood that this cost will be covered in the course of furnishing DMEPOS products to their Medicare patients. If the projected exodus of DMEPOS suppliers occurs, then what would happen to the Medicare beneficiary who presents to a physician's office with a problem or condition for which a specific item of DMEPOS would be of immediate benefit?

To consider this question further, we believe it would be useful to focus on some common clinical situations in podiatric medical practice. According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Examples of how podiatric physicians utilize DMEPOS in patient care include the following:

- A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

- A podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier because being so is no longer practical as a result of surety bond requirements, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

As should be obvious from the preceding examples, patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient. The physician might also need to supply an item at the point of service to meet the applicable standard of care. For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program and the physician might face additional liability. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

Even for non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item of DMEPOS, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination. If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the

physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

In addition to clinical considerations, there are also obvious differences in the quantities of DMEPOS products provided by physicians compared to the amounts provided by suppliers who do nothing but furnish DMEPOS products. According to 2004 Medicare data on DMEPOS services, practitioners were responsible for 3.1 percent of DMEPOS allowed charges while entities categorized as "suppliers" were responsible for 96.4 percent of those charges. Most podiatric physicians, who operate as small businesses, supply limited quantities of DMEPOS items to Medicare beneficiaries as part of quality, appropriate, and necessary patient care. Requiring physicians to obtain surety bonds to continue to supply DMEPOS to patients at the point of service will disrupt Medicare beneficiaries' access to care that is in their best interest.

The APMA believes that access and quality of care considerations, and known differences in the quantities of DMEPOS products provided by physicians and DMEPOS-only suppliers, were among the factors that led the Congress to conclude (as discussed earlier in these comments) that surety bond requirements should not be applied to physicians.

In sum, the APMA urges CMS to exempt all physicians, including podiatric physicians, from the proposed DMEPOS supplier surety bond requirements when these individuals are furnishing DMEPOS as an integral part of the care provided to their own patients.

In addition to obtaining an exemption for physicians, which is the APMA's principal concern, we wish to take this opportunity to offer the following, three additional comments:

- First, if CMS concludes that there are good policy reasons for exempting certain categories of DMEPOS suppliers from any surety bond requirements (in addition to exempting physicians) the APMA recommends that CMS defer publication of a final rule until explicit Congressional guidance on this can be obtained. Similarly, if CMS remains uncertain about Congressional intent with respect to the exemption of physicians, despite the evidence reviewed above, we again recommend deferring publication of a final rule until this matter can be resolved by the Congress. Since 10 years have now passed since enactment of the BBA surety bond provision, there seems to be no particular urgency to publishing a final rule at this time.

- Second, if and when CMS imposes a surety bond requirement on any DMEPOS suppliers, the APMA recommends that the requirement be applied at the tax identification number (TIN) or similar level of aggregation, and not at the national provider identifier (NPI) level. A supplier with several locations or with more than one NPI (for whatever the reason) should not be expected to submit more than one surety bond.

- Finally, if and when CMS imposes a surety bond requirement on any DMEPOS suppliers, the APMA recommends that the agency give the affected suppliers at least 6 months, not 60

American Podiatric
Medical Association, Inc.

days, to comply. Providing an unduly short amount of time to comply seems especially unnecessary and ill-advised when the authorizing statute was enacted a full 10 years ago.

IMPACT

The proposed rule provides a confusing array of data with respect to the number of DMEPOS suppliers that would be affected. For example, in the impact analysis, in estimating the costs of obtaining surety bonds, CMS assumes that "approximately 99,000" suppliers will be involved (and that the average annual cost of a bond will be $2,000). However, in the section of the proposed rule summarizing collection of information requirements, CMS estimates that "approximately 116,500 DMEPOS suppliers" will comply with the proposed surety bond requirements. Any final rule should make sense of the conflicting array of data.

More importantly, CMS predicts that almost all of the nearly 16,000 billing suppliers with allowed charges of less than $1,000 in fiscal year 2005 will drop out of Medicare. CMS also predicts that the majority of the 14,000 with allowed charges between $1000 and $5,000 will also drop out. To be more precise, CMS projects that "as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities, and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented." CMS also believes that "approximately 22 percent of the 15,000 DMEPOS suppliers are located in rural areas." The APMA believes that all of these projections should be cause for alarm, not support for implementing a final rule as proposed. A significant reduction in the number of DMEPOS suppliers will almost certainly have negative consequences for Medicare beneficiary access to DMEPOS, especially in rural areas. We cannot believe that this is what the Congress intended. In our view, CMS's estimated impact provides yet another rationale for deferring adoption of a final rule and for undertaking fresh consultations with the Congress now that a decade has passed since the BBA was enacted.

We hope the above comments are helpful. If you have any questions about them or need additional information from the APMA, please contact Rodney Peele, APMA's Assistant Director of Health Policy and Practice, at 301-571-9200 or via e-mail at RDPeele@apma.org.

Sincerely,

Christian A. Robertozzi, DPM
President

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Testimony of
John C. Shirvinsky
Executive Director
Pennsylvania Association of Medical Suppliers
Before the
U.S. House of Representatives
Committee on Small Business
Subcommittee on Investigations and Oversight
October 31, 2007

Mr. Chairman and Honorable Members of the U.S. House of Representatives Committee on Small Business Subcommittee on Investigations and Oversight, my name is John Shirvinsky and I am the executive director of the Pennsylvania Association of Medical Suppliers (PAMS). PAMS is America's oldest state advocacy organization representing the interests of home medical equipment (HME) providers.

About PAMS and the Promise of HME

PAMS' membership is comprised of companies that supply durable medical equipment and supplies to the public. The companies we represent are overwhelmingly small and independently owned. Our members are in the business of helping people with serious health conditions live comfortable lives in their own homes. In doing this, our members help the health system save substantial dollars.

In addition to our role as advocate, PAMS provides the forum and the opportunity for our members to receive educational programming, to promote ethical standards of practice for the HME industry in our state, and to foster the highest standards of care for the people in need of home medical equipment and supplies.

You might ask how it is that our members manage to introduce savings to an ever-more-expensive health system. The answer is that we are a low-cost alternative to some of the most expensive forms of health care, such as long-term care and hospitalization.

In Pennsylvania alone, the cost to the state's Medical Assistance (Medicaid) system to place a single individual in a long-term care facility runs an average of about $56,000 per year. In comparison, it costs about $23,000 per year to give that person the same level of care in their own homes.

But the savings potential of HME providers doesn't end as an alternative to long-term care facilities. People with long-term respiratory problems, such as COPD, can receive home treatment for an entire year for less than the cost of a single day's visit to the hospital. That's an average of about $6.65 per day for in-home oxygen care vs. a

national average in excess of $4,600 per day for a hospital stay. Our home infusion therapy providers offer a variety of life-sustaining intravenous medications, including chemotherapy, which are far more cost-effective than the alternatives of in-patient or out-patient treatments. The average cost per day of home therapy was $122, compared to $798 in the hospital and $541 in a skilled nursing facility setting.

I would respectfully urge you to remember these numbers as you and your colleagues search for ways to find savings in the Medicare and Medicaid systems. Our industry, in conjunction with home healthcare professionals, can provide individual, in-home care for roughly 40 percent of the cost of long-term institutionalization. I challenge you to find another healthcare sector that is capable of making a similar claim. And who wouldn't want to remain in their own home given the choice?

Competitive Bidding and the Small Provider

We first commend this Subcommittee for taking this opportunity to examine the impact of CMS's competitive bidding program for DME and for looking at the question, "Will small suppliers be able to compete?" That is a question that many of us have been attempting to contend with for much of this year. The question might as well be, "Will small suppliers be able to survive?" One small provider in Pittsburgh – who does about 65 percent of his business with Medicare – recently told me that this is a question that keeps him awake at night.

It is important to recognize that phrasing the question in those terms is not hyperbole. It is a sober recognition of what the competitive bidding process is and who the majority of DME providers are. Competitive bidding generally – and particularly the competitive bidding process that has been applied to DME – is an exclusionary process. It is a process that produces winners and losers; and it produces far more losers than winners. It has been one of the stated goals of the Centers for Medicare and Medicaid Services (CMS) to reduce the number of DME providers serving Medicare beneficiaries.

The HME industry is not populated by big players who have cornered the market. It is a healthy market sector that is largely made up of small, independently owned providers serving relatively small service areas. Yes, there are a number of large national and regional providers, but they are competitors and do not tend to dominate markets.

Therefore, since competitive bidding is an exclusionary process, and since the majority of providers tend to be small and independently owned, it would stand to reason that the losers – those who will find themselves precluded from further participation in meeting the DME needs of Medicare recipients – will be small, independently owned companies.

To understand how CMS structured its small provider provisions, let's refer to a CMS press release from April of 2007 describing the program:

"The final rule provides for a 30 percent target number for small supplier participation. If CMS determines after the initial evaluation of bids that there are not enough small suppliers with winning bids to meet the target goal of 30 percent in each product category, then contracts will be offered to small suppliers that submitted bids higher than bu(t) close to the winning bids. The small suppliers will have the option to accept the single payment amounts based on the winning bids until the 30 percent goal is met or there are no additional small suppliers.

"The final rule also allows small suppliers to form networks in order to participate in the bidding process, provided that these networks comply with all federal and state laws including the federal antitrust laws. In addition, small suppliers will not be required to submit bids for all product categories. As a result, small suppliers will have the flexibility of deciding for which product categories to submit bids."

So, CMS set a "30 percent target number for small bidder participation" ***if***:

- The small providers are able to meet the CMS-established qualifications for bidding; and if
- The small providers are able to demonstrate the ability to serve an entire metropolitan area even if their existing business is limited to a small portion of that area; and if
- The small providers are willing to accept a bid price lower than the one they submitted; and if
- The small supplier's bid was "close" to the winning bid.

It's hard to feel terribly secure if you are the one facing all of those "ifs." The bottom line is that CMS will try to give some market share to small providers so long as small providers are available and able to do the job for a three-year fixed price. Employment costs may not be fixed; gas prices may not be fixed; health care expenses may not be fixed; but Medicare reimbursement rates will remain fixed for three full years.

Finally, CMS set forth the possibility of small providers participating in small supplier networks for the purpose of submitting bids. This is as good of an illustration as any as to how little the folks at CMS understand about the DME industry or business in general. I'll quote the press release again: "*provided that these networks comply with all federal and state laws including the federal antitrust laws.*" So the challenge here was for several small DME providers to gather together for the purpose of submitting a combined bid at agreed-upon prices and to somehow not violate federal or state antitrust laws in the process. In other words, they needed to find a way to agree upon pricing without actually discussing or fixing prices. That's a neat trick if you can pull it off.

To the best of my knowledge, no small providers were able to successfully form such a network in the Pittsburgh competitive bidding area. In my conversations with other state associations and the American Association for Homecare, no such networks

were reported to have been formed anywhere in the country. I am confident about my information on the Pittsburgh MSA.

What small providers did do in Pittsburgh was to take the initiative to form *ad hoc* subcontracting arrangements. There was no practical way to structure a network as envisioned by CMS because there was simply too much to overcome, even if antitrust were not a consideration: the ability to rely on the performance of others not under your direct influence; the attorney fees involved in creating a network; the inability to agree on structure; different standards on things ranging from employee compensation to service standards to hours of operation.

The subcontracting arrangements were another example of necessity being the mother of invention. Faced with extinction and unable to utilize CMS' flawed networking scheme, these companies decided to take advantage of the program allowance for subcontracting arrangements to meet the needs of the request for bids (RFB). Each provider agreed that they would submit their own bids and secured letters of intent from one another to provide products and services throughout the Pittsburgh competitive bidding area.

You might say that that was a clever idea and you'd be right. But you should also wonder why it is that honest, hard-working business people need to come up with clever ideas in order to survive as providers of such important equipment and services to Americans in need.

Problems with Competitive Bidding

Competitive bidding was a bad idea from the get-go. It was inserted into the Medicare Modernization Act of 2003 in the middle of the night just prior to final passage. It was not properly vetted. It was not properly thought through. It makes pretensions about its ability to save money (on a very, very small portion of Medicare spending) that are simply unsupportable and unsustainable. It makes no account for its impact on businesses, communities, employment, product quality, quality of care or the potential for increased hospitalizations in the Medicare population that may result. It is a program that promotes the concentration of market share yet takes no notice of the inherent dangers in such concentration. Competitive bidding is a bad idea.

The CMS competitive bidding process received failing grades from Pittsburgh area providers of all types and sizes. From the many providers with whom I have spoken, it has been called flawed, ridiculous, unworkable, overwhelming, frustrating, crazy, uninformed, anti-private enterprise, absurd, disturbing and misdirected.

Prior to and during the bidding process, I fielded numerous calls from small DME providers seeking insights into the monstrosity that CMS had unleashed. The process is big, it is complicated, and it is intimidating. More than one questioned whether the time had come to close their doors. Should they finally retire? Should they find another business or seek other employment opportunities?

One of the more common complaints is that CMS simply doesn't understand the DME industry, what it is that we do, the vast array of patient services that we normally provide, and the nature of our operations.

DME is overwhelmingly a network of small to medium-sized businesses serving relatively small service areas. The planners at CMS may look at the Pittsburgh MSA as a small, homogeneous metropolitan area, but they are wrong. Most living in those areas shown on the CMS Pittsburgh Competitive Bidding Area (CBA) map (see Attachment A) may agree on their love for the Steelers, but western Pennsylvania is a quilt work of neighborhoods, communities and counties that have little to do with the city of Pittsburgh other than as a point of reference.

The Pittsburgh CBA is big. It incorporates the seven counties directly surrounding Pittsburgh and tiny bits and pieces of another seven counties. The northern reaches of the CBA have little to do with the southern. The eastern reaches have little to do with the western.

Congressman Altmire's 4th Congressional District serves as a good reference point. It forms the northwest boundary of the MCS map, shoots east across the middle of the CBA and ends in Murraysville to the east. Few Murraysville residents are inclined to do their shopping or look for medical care in Cranberry. Fewer still would be interested in traveling to Beaver Falls. While Congressman Altmire represents the interests of all of these communities, his constituents in those communities have precious little interaction with one another. Of course, CMS is seeking to change that for individuals in need of DME products and services.

Small DME providers normally serve relatively small service territories. They are unlikely to serve an entire MSA of the likes that we are talking about here. Mandating such extensive coverage, as CMS' competitive bidding does, serves as a barrier to entry. This is particularly true for those companies that may operate on the boundaries of the CBA. I recently spoke with a provider located in Cambria County (not in the CBA) who does a significant amount of business in neighboring Westmoreland County (in the CBA). He had been hoping to expand his operations further westward to eastern Allegheny County. But the competitive bidding process was far too high a hurdle for a small provider on the fringes of the CBA to surmount, so he chose not to bid. His services will soon no longer be an option for his Westmoreland County patients.

So it is easy to see in this example how the DME competitive bidding process can stop a company from growing. But it is also restricting patient choice by eliminating competitors from the marketplace. And once you eliminate competition, the stage is set for service to suffer. The few competitors who remain will be hard-pressed to remain financially viable under the initial contract terms and something will have to give. As operating costs continue to increase and margins fall, service becomes a likely target for cutbacks.

The problems experienced by first-round bidders with the CMS computer system have been well documented and don't warrant any further comment from me other than to say that they were real and added significantly to the time and cost of bidding.

Other problems identified by bidders within the Pittsburgh CBA were:

- The process was convoluted and required companies to bid on items and services even if these are not items that the provider normally deals in. A prime example of this is oxygen. Medicare reimburses for oxygen at a single rate even though the acquisition and labor costs vary greatly among the different types of oxygen systems. Because liquid oxygen has the highest costs associated with it, many providers got out of the liquid oxygen business many years ago. But in order to qualify to bid for any oxygen, you had to bid for all oxygen. This was a hurdle for many companies.
- Competitive bidding is certain to create frustration for beneficiaries. Today a beneficiary is likely to have a single provider serving all of their DME needs whether it be mobility, respiratory or hospital beds. Under the CMS plan, a sick, elderly person may need to deal with a different company for each need depending on how the bids are awarded. In the event of an emergency, this may prove catastrophic should the individual be unable to remember which provider supplies which service. If this program results in an increase in emergency room visits or increased hospitalizations, it is not likely to save any money at all.
- The inclusion of complex rehab may rank as the single most inappropriate provision in the DME competitive bidding program. It is called complex rehab for a reason – it is complex. When a healthy teenager is suddenly rendered quadriplegic due to a severed spinal column from a violent automobile accident, it is a life sentence. It has been the policy of our nation to give such young Americans a chance at life. A chance at continuing with their education, a chance at a career, a chance at having a family and a home. A number of federal initiatives, including the Americans with Disabilities Act and the New Freedom Initiative, seek to ensure that people with disabilities face no further obstacles to full participation in our economy and society. But for such individuals, that chance starts with getting fitted for a power wheelchair that will be their means of mobility for the rest of their lives. It is not a simple process. Each case is different. The size of the chair differs; the seating components differ; the means of steering and moving the chair differs; and the process of acclimating the individual person to the individual chair differs. It makes absolutely no sense to attempt to place such a necessarily individualized process into a one-size-fits-all box. It is precisely because this is high-priced equipment that great care should be taken to get it right the first time. Attempting to force DME providers to supply such complex and individualized equipment "on the cheap" will likely cost more money in the long run.

- Although it is hard to say whether the small business set aside will prove successful or not, it is easy to note that the minority set-aside will not bear fruit. There was no provision made for minority or women-owned enterprises.
- No one seems to have a high confidence level in whether they complied with all program provisions or not. The financial requirements were unclear as were various other program elements such as the definition of capacity.
- Finally, our members are unsure about who it is that they are competing against. Since anyone is free to bid in any CBA, some very large concerns are said to have submitted bids in every CBA, even those in which they have no current operations. Since they had already done the work of preparing bids elsewhere, why not simply submit bids everywhere? That may turn out to be a good gambit for those with the wherewithal to do so, but it isn't very good news for those small local companies who have been faithfully providing quality service to their patients for many years.

Perhaps the only positive thing that we have to say about the process is that it gave CMS the opportunity to finally embrace the concept of requiring accreditation as a prerequisite to participating as a Medicare DME provider. The HME industry has promoted the accreditation concept as a way of weeding illegitimate "suppliers" out of the system. There has been a great deal of attention paid to DME fraud over the years, and accreditation is a great tool for ensuring that only legitimate providers do business with Medicare. It is unfortunate that CMS resisted this idea for as long as it did. There should be no room for fraud in this system, and the HME industry supports the use of the accreditation tool as a means of separating the good providers from the bad.

Is Competitive Bidding Good Business or Bad News?

Acting CMS Administrator Kerry Weems recently referred to the DME competitive bidding process as one that used "market-based competition to increase efficiency in Medicare." He went on to declare, based on the DME experience, that "competitive bidding can reduce spending, while assuring access and quality."

There has been absolutely no information released to the public that any meaningful savings have been realized as a result of the DMEPOS competitive bidding exercise. CMS hasn't released information on how many DME providers submitted bids, nor have they indicated whether the initial bids were sufficient to ensure that each product category is adequately covered in each bidding area. There is no guarantee that every provider selected will be willing to commit at the CMS fixed price for three years, particularly if that price is lower than a company's bid price.

It is highly unlikely that CMS is in a position to offer DME patients living in competitive bidding areas any realistic assurances on either access or quality. It would be nice if they would come forward with any information at all. It would be nice to have an accounting how much this initiative has cost taxpayers to date. Since DME represents

such a miniscule portion of the overall Medicare budget, it would be interesting to see whether the funds invested to date are sufficient to justify the projected savings.

But let's focus for a moment on CMS' contention that DME competitive bidding represents a "market-based efficiency." It is, at best, dubious to suggest that this program represents anything close to market economics or that it is an exercise in running government like a business.

It's important to remember that government is not a business and its role in a free market economy, while extensive, is best limited to the things that it is designed to do. This would include providing the legal structure for businesses to operate, maintaining competition (guarding against monopolies and market concentration), the redistribution of income through programs such as Medicare, and providing public goods and services.

Competitive bidding is a tool that can be used to great effect by government so long as it is carefully targeted and promotes competition. Think highway and facility construction projects or even office supplies or local trash collection.

The CMS DME competitive bidding process is none of these things. It is complex, far-reaching and burdensome. It is a government-sponsored scheme to eliminate competition by dismantling a national network of HME providers that has reliably serviced the home health needs of Medicare patients for decades. Medicare beneficiaries, CMS and this Congress will live to regret the day that this network of independent DME providers was dismantled as a result of this ill-considered program.

If Medicare were a private insurance plan, it would be the dominant insurer in this market. If that dominant insurer decided that it only wanted to deal with five or six DME providers in a metropolitan area instead of 100, that would be considered market manipulation. The government would investigate and rightly so. CMS is attempting to manipulate this market for purposes that will not result in savings, that will not ensure better service for people in need, that will result in layoffs, that will result in small business closings and that will result in the loss of tax revenues to state and local governments.

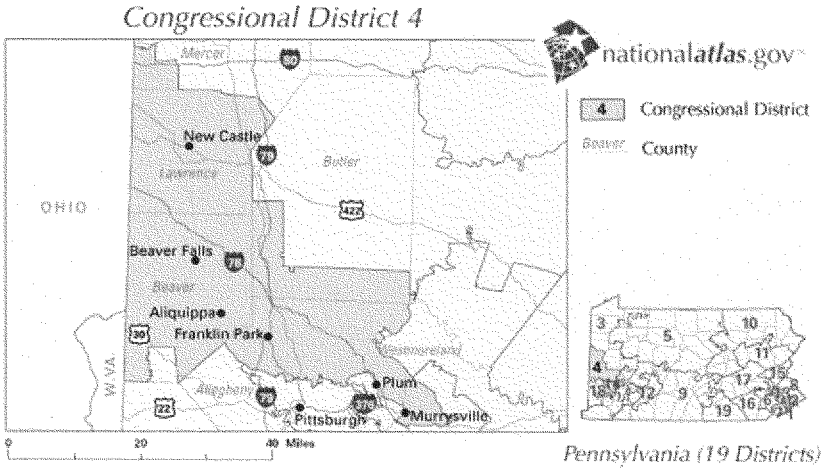
The Medicare population is growing larger and older with each passing year. For the HME industry, that means a growing market. Under free-market economic theory, that should mean that more competitors should be entering this market, helping to drive down or stabilize prices in the face of increasing demand.

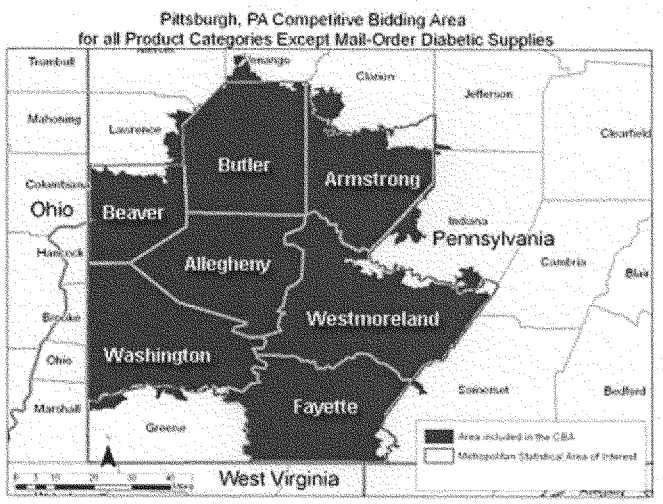
It is inconceivable that it would be the U.S. government that would come forward with a scheme to concentrate market share and eliminate competition given such conditions. What CMS is doing is a formula for certain higher prices down the road. Competitive bidding for DMEPOS is not good business. It is bad news. The most responsible thing that this Congress can do on this count is to admit that a previous Congress made an error in approving a poorly considered provision. I urge this Subcommittee to support the repeal of competitive bidding and to set this nation's small

and independently owned HME providers free to meet the needs of America's aging population.

We thank you for this opportunity to testify.

Attachment A
Pennsylvania Assn. of Medcial Suppliers





STATEMENT OF

Carol Gilligan, President

Health Aid of Ohio, Inc.,
Cleveland, Ohio

Before the

House Committee on Small Business

Subcommittee on Investigations and Oversight

"Competitive Bidding for Durable Medical Equipment: Will Small Suppliers Be Able to Compete?"

October 31, 2007

Good morning Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to talk with you today about the Medicare Program and its implementation of the competitive acquisition program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), and its impact on my small business and the consumers I serve.

Introduction

My name is Carol Gilligan, and I am president of a health care company called Health Aid of Ohio, in Cleveland Ohio. I started my small business in 1984 to serve seniors and people with disabilities. My company primarily provides what we call "complex rehab" equipment and services to people with specialized needs. We provide sophisticated and customized complex wheelchairs and accessories to people who have very severe and individualized needs. In addition, we provide home oxygen therapy and other respiratory services, and we offer an array of home medical equipment such as beds, walkers and other items that consumers with acute or chronic conditions use to enable them to live in their homes, rather than in more costly institutional settings.

I started my small business over 20 years ago after meeting a girl in my neighborhood who has a rare form of muscular dystrophy. My business was inspired by my desire to be able to really help people who have special needs and mobility limitations. We serve about 5400 consumers out of our location. Approximately 25 percent of my business is from Medicare beneficiaries, and the remaining 75 percent is from Medicaid recipients or private pay consumers. This year, I was honored to be awarded the "Best Rehab Provider in the United States" by HME News, an industry trade publication.

Serving High End Rehab Consumers

I'd like to explain the types of services my company provides to consumers and how the bidding program will impact my business and consumers.

Provision of complex rehab technology is not a commodity. Complex Rehab and Assistive Technology consists of highly individualized products and services that are prescribed by a physician and provided to individuals by specially trained and credentialed members of the rehab technology profession. It is different from traditional durable medical equipment products in that the rehab products are evaluated, fitted, configured, adjusted or programmed to accommodate each individual's specific and unique medical needs; taking into consideration the individual's medical history, diagnosis and disease progression, functional needs, anatomical requirements and anomalies as well as typical environments that the individual incurs throughout the course of their daily activities..

Imposing a competitive bidding process on complex rehabilitative services will substantially undercut the quality of life for thousands of persons with disabilities. Each new consumer our company serves requires a different evaluation and assessment, measuring, fitting, simulations and demonstrations, mixing and matching of products, refitting and then additional modifications. The service component inherent in each specialized piece of equipment is very high, and simply is not amenable to the bidding structure being implemented by the Centers for Medicare and Medicaid Services.

I am accompanied today by my friend, David T. Williams of Amherst Ohio. David is an excellent example of what all goes into the process of providing complex rehab.

To understand why his wheelchair is so complex you need to understand David's clinical picture. In 1975 David was diagnosed with Multiple Sclerosis. Recent advances in diagnostic methodologies and technology have refined that diagnosis to be Chronic Progressive Multiple Sclerosis. This form of Multiple Sclerosis is characterized by acute exacerbations of the disease resulting in the formation of scar tissue in various locations in the brain and spinal cord. This in turn causes a wide variety of symptoms.

In David's case the location of multiple lesions in his spinal cord have resulted in the following symptoms/disabilities:

- quadriplegia (paralysis and/or paraparesis of all four extremities);
- severe chronic neuropathic pain;
- partial paralysis of the diaphragm resulting in periodic hypoxia;
- partial paralysis of the vocal folds interfering with speech and causing difficulty with swallowing;
- loss of peripheral vision and depth perception;
- central sleep apnea;
- neurogenic bladder and bowel resulting in urostomy;
- a history of pressure sores/decubitus ulcers;
- chronic fatigue syndrome; and,
- a history of several episodes of deep vein thrombosis and pulmonary embolisms.

The process starts with a thorough review of his medical record and a complete and detailed evaluation by the multidisciplinary "wheelchair seating clinic" at the Mellen Center for Multiple Sclerosis Treatment and Research of the Cleveland Clinic Foundation. Based on this evaluation David's neurologist prescribed a motorized/power wheelchair that would provide him with pressure management, respiratory relief when necessary, postural stability, adductor spasticity control and the ability to periodically reposition and elevate his legs.

The Certified Rehab Technology Specialists conducted an environmental assessment and, based on the doctor's prescription and the recommendations of the various health professionals in the seating clinic, ordered the following components to provide David with an appropriate wheelchair:

- motorized/power wheelchair base;
- transportation securement system;
- joystick style driver control with tremor dampening and "mushroom cap" style control knob;
- power elevating leg rests; and,
- powered seating system with the following functions:
    - tilt and recline with zero sheer functionality;
    - elevate seat height;
    - trough-style armrests;
    - trunk lateral supports;

- adductor positioning device;
- pelvic stabilizing/positioning seatbelt;
- tall contoured back; and,
- headrest.

In order to meet David's unique needs, physiology, height, weight, abilities and disabilities the wheelchair that you see David driving today is built from components procured from seven different manufacturers. The component parts were assembled by a rehab technology company who had to fabricate some of the hardware needed to blend the different components into one system. The "wheelchair" was then delivered to David and several field adjustments were made during multiple visits to David's home.

Between the time David notified the staff of the seating clinic which rehab technology company he wished to have provide his new system and today, the health care team has spent more than 45 hours over three months doing the environmental assessment, working with David to see the kinds of things he must do every day to maintain the best possible quality of life (and perform all the "mobility related activities of daily living"), ordering the components, supervising the assembly, fitting and adjusting the product and in training David in proper use of the system.

David's case is not unique. It represents the kind of challenge rehab technology companies see on a regular basis.

CMS' Implementation of the DMEPOS Bid Program

In CMS' bid program, if the bid price ends up being unreasonably low, consumers will suffer. For example, these consumers typically need sophisticated seating systems to prevent pressure sores. Seat and back cushions are customized to the individual's specific body to minimize the possibility of decubitus ulcers. If the bid price is unreasonably low, based upon low-ball bidders, consumers will likely not have access to the more expensive customized cushions that prevent pressure sores, and will likely end up being hospitalized as result. Healing decubitus ulcers in the hospital can cost up to seventy thousand dollars. This is truly penny wise and pound foolish policy.

In order to provide the most medically appropriate items to consumers, we must employ specially trained personnel. My employees and the therapists we work with are specially trained to assess and evaluate consumers with severe needs. For example, we have on staff three Assistive Technology Suppliers, with an additional three in training. These are individuals who have been trained and tested to ensure they have the requisite knowledge, experience and expertise to provide the most clinically appropriate items. I have brought here today a custom seat and back mold so you can see the type of detail and customization required for one component of a consumer's mobility system.

Because of the large service component necessary for fitting and modifying complex rehab technology, these items are simply not appropriate for a competitive bid process that is designed to attract low-ball bids on commodity items. Most importantly, if services are reduced or if the provider is unskilled or inexperienced, consumers' conditions will be exacerbated, requiring more extensive medical intervention.

In the bidding program, CMS requires that suppliers bid on the entire complex rehab category. While suppliers have to bid on every code in a product category, they are not required to make available all technology that falls under a particular code. Many of the codes include a wide range of items with varying costs. As a result, this bidding system that encourages low-ball bids will ensure that more complex items that are highly configurable will be very difficult if not impossible for consumers to obtain.

With this bidding program, the government is creating a "one size fits all" category for products, which will likely have the effect of coercing patients into using improper devices. The consumers are the ones who will lose because an ill-fitting device further decreases patients' mobility and quality of life.

My Experience Submitting Bids

In early April this year, the Centers for Medicare and Medicaid Services, or CMS, announced that my service area, Cleveland, would be one of the initial ten metropolitan areas for this bidding program. CMS also announced that most of the items and services I provide would be included in the bid program. Specifically, high end rehab wheelchairs, consumer mobility, oxygen therapy, hospital beds and other items that my company provides would be included in the bid program. What this means for my company is that my company would need to be a winning bidder for each of the product categories in order to be able to serve Medicare beneficiaries once the program goes live, scheduled for July 1 2008.

I therefore had no choice but to submit a bid, unless I wanted to close my business. I submitted bids on seven of the nine product categories for the Cleveland area: complex rehab power wheelchairs, standard power wheelchairs, oxygen, continuous positive air pressure devices (called CPAPs) and respiratory assist devices (or RADs), hospital beds, walkers, and negative pressure wound therapy pumps.

I'd like to explain how the bid submission process worked for one product category, the "Complex Rehabilitative Power Wheelchairs and Related Accessories" category. In this category, there are approximately 150 separate HCPCS codes. The codes in this product category include complex wheelchairs, positioning accessories, special needs cushions (for example to prevent decubitus ulcers), electronic controllers to allow differently abled people to control their wheelchair according to their individual capabilities, and other items. For each of the 150 codes, my company submitted one price, even though often multiple items with different price points are in each code. For each code, we needed to state a "capacity," that is, how many of these items we could provide to beneficiaries during the three year contract period.

Each price we submitted for each code could not, according to CMS rules, exceed the current Medicare fee schedule amount. Therefore, if market pricing is above the fee schedule amount, the bid process prevents bids from reflecting real market prices. This does not make sense. If this program is based upon the belief that the market will set the prices, then there should be no artificial ceiling of what price we could submit in my bid.

In order to submit a bid based upon a complete understanding of my total delivered costs, I hired a consultant to help me conduct an "activity-based costing" analysis. While this was a worthwhile undertaking for us to understand better our "total delivered costs" for each product line we provide, the prices we submitted in our bids were not entirely based upon this rational analysis. Instead, my company's bid prices were based more upon an assessment of what we thought the competition would submit, rather than a realistic assessment of my business financials. This is because, as a small business, we just don't have access to the volume-based pricing that large national companies do, and in order to have a chance to be a winning bidder, we felt we had to lower our bid prices just to have a chance at surviving.

The other scenario we faced in the bid process was the emerging "low–bidding opportunist mentality" that emerged. This "bidder" looked upon the Cleveland market as a place to expand their market share. This new competitor did not have any market share or did not incur the expense of having an existing business and patient care base. Instead, the entity submitted a very low and if they ended up being a contract supplier, they would set up a business without all of the services we currently provide. They would then conduct a quick sell to a national company should there be any value; otherwise, they would just dabble in that product category. The fact that this scenario could occur was caused by CMS' lack of public criteria regarding how CMS would evaluate a prospective business' plan to operate a viable business in the area.

Another deficiency of the bid evaluation process is that CMS will set the bid price based upon the median of potential winners. That is, once CMS has established a cut of suppliers (the "pivotal bid" supplier), CMS will set the bid price at the median submitted bid of potential contract suppliers. If all of those suppliers decide to be contract suppliers, then half of the suppliers will be forced to accept a bid price less than what they submitted as their best price. In contrast, in the demonstrations CMS conducted in Florida and Texas, the bid price was set at the pivotal bid, so each potential contract supplier would receive a bid price that was at or above their submitted bid. This also contrasts to the private sector where your submitted bid is what you get paid. CMS's decision to make the bid price at the median of potential contract suppliers in and of itself makes it increasingly difficult for any supplier whose submitted bid was above the median of potential winners to maintain a financially viable business.

Another significant difficulty in submitting bids is that there is no guarantee of any particular volume if we actually win the bid. This is in direct contrast to how the private market works. For example, if I know that my company will serve 500 home oxygen patients, we can put together a price that is rationally based upon a known volume. In this case, however, if we win, we will still be competing against other winners, and there is no guarantee of any set number of people that we will serve. Therefore, CMS's system does not allow bidders to submit rational bid amounts based upon prospective volume.

In CMS' final rule, it estimated that on average, it will cost a supplier $2303.16 to submit its bids. This estimate is far from my experience as a small business. We began preparing to submit bids as soon as CMS announced in early April that Cleveland would be a bid area, and worked through the final deadline of September 25. We spent considerable time and resources, both internally and externally to prepare the bids. In total, we spent over thirteen thousand dollars to submit the bids for seven product categories. That figure includes $3000 for an

activity based costing consultant and $4000 for an outside accountant, plus over 300 hours of staff time.

If My Company Loses the Bid

If my company loses the bid, the impacts will be far greater than just losing Medicare business. I will likely lose most of my other business for those product categories because referral sources prefer to refer to providers who can take all business, not just patients who have a particular payor. In addition, state Medicaid programs and private payors will likely adopt the new lower Medicare bid fees, further negatively impacting any remaining business. Therefore, the majority of my business would be lost, forcing me to close my doors.

In its final rule, CMS discussed ways in which it was attempting to address the problems that small businesses would specifically encounter in this program. In reality, none of CMS' attempts will actually do anything to alleviate the issues that small business encounters with this program.

First, CMS changed its definition of "small business" from $6 million in annual revenues to $3.5 million. This is inconsistent with the Small Business Administration's definition for our industry, and my understanding of our industry, based upon over 20 years experience. CMS should have maintained the SBA definition at $6 million.

Second, CMS set a target, not a requirement, that 30 percent of the winning suppliers be small business. Therefore, if none of the initial winning suppliers them are small business, CMS will ask small businesses whose bids were too high if they want to participate at the bid rate. Because price is the primary determinant of being a winning bidder; if all small business bidders bid prices are above the winning bid amount, then to accept the bid amount will mean taking a financial loss on a product category. No small provider can afford that.

Third, CMS has set a target, not a requirement, that there be at least five winning suppliers in each product category. I am not sure how that addresses small business concerns because for each product category there are significantly more than five competitors in my market. In fact, there are five very large providers in each of the product categories in the Cleveland area, none of which are small business.

Fourth, CMS established a network scenario that is theoretically geared to help small business. The logistics and legal issues associated with small business forming networks are substantial. For that reason, I doubt that any networks were formed in any of the initial ten bid areas.

Overall, while CMS made some noise about addressing small business issues, I don't believe that CMS has taken any meaningful steps to address the special needs of small business and our ability to participate in this program. I am very concerned about my company's ability to win one or more of the bids, and even if CMS asks us as a small business to participate to meet its 30% small business target, I sincerely doubt that the bid prices will represent a rational business decision for my company. In the end, whether I win or lose the bids, my company will be severely impacted, and may not be able to survive.

Conclusion

As a small business, I believe we are disproportionately negatively impacted by this bidding program. Mr. Chairman and Members of the Subcommittee, there are two bills that have been introduced, H.R. 1845 and H.R. 2231 that would make reasonable changes to how CMS implements this bidding program, and that would begin to address some of the problems faced by small business. I strongly urge this Committee to actively support these measures.

Thank you for the opportunity to appear here today. I would be happy to answer any questions.

House Committee on Small Business
Subcommittee on Investigations and Oversight

"Competitive Bidding for Durable Medical Equipment: Will Small Suppliers Be Able to Compete?"

Wednesday, October 31, 2007

Testimony of Ms. Georgetta Blackburn,
Vice President, Government Relations and Legislative Affairs
BLACKBURN'S Physicians Pharmacy

Good afternoon, Mr. Chairman and distinguished members of the subcommittee. My name is Georgie Blackburn and I am pleased to be here today on behalf of the American Association for Homecare where I serve on its board of directors and executive committee.

I am very delighted that the subcommittee has called for this important hearing aimed at examining the Medicare competitive bidding program and its impact on patients and small providers who provide homecare equipment and services to millions of Americans.

The American Association for Homecare is the national association representing the interests of home medical equipment providers. AAHomecare members include a cross-section of manufacturers and providers that make or furnish durable medical equipment, prosthetics, orthotics and medical supplies to Medicare beneficiaries in their homes. Our members are proud to be part of the continuum of care that assures that Medicare beneficiaries receive cost-effective, safe, and reliable homecare products and services in their homes.

I am also Vice President of Government Relations and Legislative Affairs for Blackburn's—a home medical equipment company based in the Pittsburgh metropolitan area. Blackburn's has been in business for more than 70 years and has 150 employees serving eastern Ohio, western Pennsylvania, northwestern West Virginia and western New York. My homecare company offers products and services specifically tailored to each patient encompassing all levels of medical equipment, pharmacy, respiratory therapy, support surfaces, power mobility, specialty products, bariatric equipment and medical supplies.

Who Requires Homecare?

We are very concerned with the impact competitive bidding will have not only on the small provider community but on the ability of providers to meet the needs of their patients. Let me describe some of the people who receive homecare services from members of the American Association for Homecare.

The typical Medicare home oxygen beneficiary is a woman in her seventies who suffers from late-stage chronic obstructive pulmonary disease (COPD) with severe low levels of oxygen in her blood. COPD is the only leading cause of death for which both prevalence and mortality are rising. COPD is a chronic, debilitating disease characterized by severe airflow limitation resulting from chronic inflammation of the airways and a decrease in functional lung tissue.

Medicare beneficiaries who use a power wheelchair are seniors and Americans with disabilities that have life-long debilitating conditions such as multiple sclerosis, Lou Gehrig's disease, cerebral palsy, traumatic brain injuries and

spinal cord injuries. Power mobility devices help these individuals live at home with independence rather than in an institutional setting.

This program will impact our parents, our grandparents and other Americans who are eligible for the Medicare program. It is with these thoughts in mind that we believe a careful and methodical approach must be taken so we do not undermine the standard of care that patients have come to expect from their homecare providers.

Impact on Home Medical Equipment Suppliers

Blackburn's has had a very difficult but not unique experience with the new competitive bidding program. We reside in one of the 10 initial areas where competitive bidding is being implemented. My company has struggled to submit a bid on all nine of the product categories subject to bidding in the Pittsburgh area. The bid system was extremely complex and confusing, which can be illustrated by the extensive time it took Blackburn's to submit our bids and the lack of participation from the provider community. We also received conflicting guidance from Medicare and its contractors. And even though we worked diligently to determine the costs of providing services to our patients, due to the service component inherent with the care we provide, our bids can only be deemed a guestimate beyond our costs.

And the risks to providers cannot be overstated. If we are not selected as a contracted provider, the survival of our company will be in jeopardy. The jobs we sustain will be dramatically cut back or lost entirely and the Medicare patients that rely on our equipment and services will be forced to find another provider.

It is important to note that Medicare providers operate in a competitive environment already. Providers not only try to negotiate the best price of the equipment from manufacturers but they also compete on the basis of quality and service. Small businesses must compete primarily on quality of service since they do not have the market size to negotiate on prices from manufacturers.

This competitive bidding system will stifle competition over the long term because the government is going to make a determination of what the demand for services is, and then, rather than let the marketplace determine how many providers are necessary to support that demand, the government is going to make that decision for us.

Small homecare providers are not only the backbone of the American Association for Homecare, representing more than 80 percent of our membership, but small homecare providers are a crucial component of our nation's healthcare infrastructure. They provide home medical equipment in every area of the country.

In southern California, Medicare homecare providers have worked tirelessly to serve the healthcare needs of many Americans who were under threat from the recent fires. Homecare providers prepare and respond to emergencies throughout the country whether it is an ice storm, hurricane or the threat of a devastating pandemic flu. In California, homecare providers reached out to their patients, evacuation centers and their referral sources to ensure that they had the necessary medical equipment and services such as oxygen and ventilators needed for survival. If there is not an adequate supply of providers, patients will be harmed when they are at their most vulnerable.

And HME providers not only do this during national emergencies and crises but on an everyday basis where our work goes relatively unnoticed. We help people remain in their homes with family rather than in a hospital or other institutional setting. Health and Human Services Secretary Michael Leavitt has called for greater use of home and community-based care in Medicaid because "it's not only where people want to be served, but it's radically more efficient." We believe the same principle holds true for Medicare.

We need to protect this valuable benefit, which is now threatened by competitive bidding.

Goals

The Association's primary goal is to ensure Medicare beneficiaries have appropriate access to home medical equipment that meets their medical needs.

The Association also believes that patients should have a choice in choosing who provides them with their healthcare services and equipment. Since Medicare was first created, beneficiaries have been able to choose their healthcare provider. This is about to change because of this program.

Under the Medicare competitive bidding program, providers must submit bids to CMS in a competition to provide items and services to Medicare beneficiaries at a reduced reimbursement rate. Providers who meet Medicare participation requirements and whose bids are deemed low enough by the government will be selected to provide competitively bid DMEPOS items and services to Medicare beneficiaries.

Those who are not selected as winning bidders, as a general rule, will not be able to provide competitively bid services to Medicare beneficiaries. Since Medicare typically makes up between 35-50 percent of a small homecare provider's practice, losing the ability to provide competitively bid items for the three-year contract period is essentially a death knell to these providers.

The competitive bidding rules designed by the Centers for Medicare and Medicaid Services (CMS) are stacked against the small provider. Smaller DME providers lack the economies of scale to negotiate lower prices or the physical size to cover an entire metropolitan statistical area (MSA).

Even with the small business protections included as part of the program such as the ability to form networks or the 30 percent set-aside for small businesses, the program will still radically reduce the number of providers that exist today. In the long-run, this will lead to less competition in this sector, not more. It is entirely possible that based on the government's criteria, a competitively bid area could be serviced by only eight providers—five large companies and three small businesses. And it is entirely possible there could be less than eight for a specific product class.

Moreover, there is concern that if the private sector adopts Medicare payment policies as their own, it is possible that private payors will allow only those providers, who accept a winning bid, to continue to provide services under private plans. If this happens, no small provider who did not win a bid will be able to remain in business. The government will have accidentally eliminated any competition for future rounds of competitive bidding.

Greater protection, more fairness, and a greater willingness to expect the unexpected is necessary for small providers so that we do not dismantle this segment of the healthcare infrastructure because once the damage is done, it will be extremely difficult, if not impossible, to correct.

Recommendations

The Association has advocated for a date-certain deadline to be announced by CMS at which time all providers would be required to be accredited. This would help ensure quality and reduce opportunities for fraud and abuse.

We have pressed CMS to implement more stringent quality standards than the ones initially developed and implemented by CMS. Adherence to these standards should be a condition of Medicare participation enforced through accreditation in order to ensure a high level of care.

Both these recommendations have not been fully addressed by CMS.

Finally, the Association supports modest changes to the program contained in H.R. 1845, the Durable Medical Equipment Access Act of 2007, introduced by Representatives John Tanner and David Hobson. This bill will take necessary steps to protect both patients, who require home medical equipment and the Medicare providers of these items and services. And it has strong bipartisan support with more than 130 members of Congress.

This bill does not repeal the competitive bidding process for durable medical equipment (DME). Rather, it makes sensible changes to its structure in order to ensure beneficiaries have access to home medical equipment; it protects small providers of quality DME items, therapies, and services; and it fosters a dynamic marketplace for Medicare-reimbursed DME that can be sustained over time.

Specifically, H.R. 1845 would:

1. **Exempt smaller, rural areas from being subjected to competitive bidding**.

   The United States Congress specifically gave CMS the authority to exempt rural areas and urban areas with low population from competitive bidding for a reason. It is important to ensure that competitive bidding is not implemented in areas that lack the number of providers to support it.

2. **Allow all providers who meet Medicare participation standards and who have submitted a bid to continue to provide competitively bid items and services at the bid rate established by CMS.**

   This provision would ensure that beneficiaries have access to a choice of providers and would foster an environment where providers work to enhance services in order to gain market share.

   Under the current design, there is no incentive to maintain and improve services once a provider wins a bid. Moreover, there will be cases where beneficiaries with several homecare needs may be forced to go to multiple providers. It is entirely possible that a patient on oxygen therapy, who requires a power wheelchair and a hospital bed, may be required to go to three separate providers for his or her homecare needs.

   The program, as designed, also will force hospital discharge planners to order multiple products for one patient from multiple providers. Patients will be serviced by multiple providers and will receive co-payment billings from various sources rather than just one, complicating matters for many elderly.

   Competitive bidding should not create barriers or hardships for patients who are prescribed covered Medicare items and services.

3. **Restore the rights of participating providers to administrative and judicial review.**

The process for submitting a bid in round one was extremely complex, confusing and fraught with problems. Most providers are unsure if their bid was completed correctly. The review of submitted bids by CMS and its contractors is also likely to be prone to human error.

Right now, providers have no recourse if a mistake is made in calculating the contract award reimbursement rate or in awarding a contract. An error can result in the loss of a bid. Restoring due process rights for providers will ensure a higher level of confidence in the program while providing a reasonable mechanism for those businesses that made an unintentional mistake or whose bid was incorrectly handled to address the mistake.

4. **Exempt items and services unless savings of at least 10 percent can be demonstrated.**

   CMS should be required to show that competitive bidding saves both the taxpayer and the government money while, at the same time, not arbitrarily reducing the number of providers eligible to furnish homecare items and services. Without a specific savings target, applying competitive bidding to those items and services where significant savings cannot be achieved may lead to a program that is more costly to administer than its primary goals of reducing payments, increasing quality and limiting the number of providers in the marketplace.

Conclusion

Homecare providers across the country are working to provide high quality items and services to Medicare and other patients. Yet the risks posed by the current design of the Medicare competitive bidding program, particularly to small providers, has the potential to vastly undermine the standard of care, quality of care, choice of provider and access to items and services that beneficiaries need.

We look forward to working with this Committee and its staff to address small business concerns raised by the Medicare competitive bidding program. We also hope to work with Committee members to address provisions outlined in H.R. 1845.

Thank you for the opportunity to testify today.

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HOUSE SMALL BUSINESS

SUBCOMMITTEE ON

INVESTIGATIONS AND OVERSIGHT

OCTOBER 31, 2007

STATEMENT BY

RICHARD SAXON

PRESIDENT AND CEO, BIOMEDICAL LIFE SYSTEMS, INC. (BMLS)

ON BEHALF OF
THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

We thank the Subcommittee for holding this important hearing today on Medicare's implementation of the 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 and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than $30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the $86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of our populace, in 2006 the industry employed 357,700 workers; paid $21.5 billion in salaries; and shipped $123 billion worth of products. The national impacts of this industry were even more substantial. Taking into account the national multiplier impacts, the industry created (direct plus indirect plus stimulated impacts): 1.96 million jobs; payrolls that totaled $93 billion; and $355 billion in shipments/sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intensive competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible. Innovations specifically within the DMEPOS sector allow patients to transition to less costly home care settings, where treatment continues while enabling them the independence of living in their home.

Patient Access to Innovation

Access to quality DMEPOS and related services can often mean the difference between a patient being able to remain in their own home or being admitted to the more expensive (and in consequence higher cost to the Medicare program) treatment care of a nursing home or hospital. DMEPOS products enable providers to give essential care to many of the frailest and sickest Medicare patients.

The medical device industry has developed a wide array of DMEPOS products to meet the patient care needs of many complex conditions. A bidding process that limits the number of suppliers providing access to these technologies may also threaten patients' access to better-technology and customized DMEPOS products. Most importantly, it limits the ability of smaller manufacturers to compete to supply these innovative and unique technologies.

To deliver this value to patients, our industry invests heavily in research and development (R&D). Today, our industry leads global medical technology R&D, both in terms of innovation

as well as investment. The level of R&D spending in the medical devices and diagnostic industry, as a percent of sales, more than doubled during the 1990s – increasing from 5.4% in 1990 to 8.4% in 1995 and over 11% last year. In absolute terms, R&D spending has increased 20% on a cumulative annual basis since 1990. Our industry's level of spending on R&D is more than three times the overall U.S. average. If competitive bidding reduces the prices for DMEPOS products to a point where the ability to reinvest in additional R & D is eliminated, the patient will suffer. CMS must take this into consideration with necessary safeguards in development of the competitive bidding program for DMEPOS.

Medicare's Competitive Acquisition Program

As you know, Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), included provisions that require the Centers for Medicare & Medicaid Services (CMS) to implement a competitive acquisition program for DMEPOS. This new program transitions reimbursements for DMEPOS from the current fee schedule to amounts that are set through a bidding process between CMS and suppliers in defined Metropolitan Statistical Areas (MSAs). In doing so, the new payment system changes Medicare's basic premise from beneficiaries having access to "any willing provider" to a selection process that over time will significantly reduce the number of accessible suppliers.

The Balanced Budget Act of 1997 (BBA) authorized CMS to conduct five, three-year competitive bidding demonstration projects. CMS only conducted demonstrations at two sites (Dade County, Florida and San Antonio, Texas), testing only eight products. The details of designing and implementing these projects were largely left to CMS.

Given this very limited test of competitive bidding, the medical device industry – companies both large and small – joined others to voice concerns about the potential impact for innovators and the patients for whom we develop the devices. We recommended a number of provisions during consideration of the MMA to assure beneficiary access to DMEPOS products and related services prescribed by their physicians, including:

- A patient advisory and oversight committee to allow stakeholders to provide input during design and implementation of the program;
- An open and transparent bidding process;
- A requirement that multiple suppliers be accepted as "winning" bidders to ensure there are sufficient numbers of suppliers to meet patient needs;
- Provisions to ensure beneficiaries have access to new technologies that come in to the marketplace after the program begins;
- Safeguards to ensure beneficiary choice is preserved;
- Methods by which to monitor and evaluate the program and its impact on beneficiary access, quality of care, market competitiveness, and patient satisfaction.

The MMA did require the establishment of a Public Advisory and Oversight Committee (PAOC) to allow for stakeholder discussions on the implementation of the program. We believe it has been a helpful tool during the implementation process, but we are concerned that a number of our other recommendations are still not being addressed. We continue to advocate for changes to the program as it is being implemented to ensure continued patient access to the array of life-enhancing and life sustaining technologies they may need.

Recommendations for Improving the Competitive Acquisition Program

Due to its direct impact on daily patient care, the DMEPOS competitive acquisition program must be carefully implemented with significant attention to detail, especially the impact on patients. We appreciate your willingness to listen to our concerns and to work with manufacturers and suppliers to ensure that Medicare beneficiaries continue to receive high quality DMEPOS. We recommend the following actions be taken by Congress or CMS:

- **Report to Congress**. The MMA requires a report to Congress by July 1, 2009 on the competitive acquisition program. We request that the PAOC be allowed to make recommendations to CMS on report parameters, and we believe these parameters should include clinical outcomes, quality measures, measures to assess beneficiary access to the range of affected technologies, potential impact on other Medicare services (such as hospitalizations) as a result of the competitive bidding program, specific impact on cost-savings, and the impact on number the of DMEPOS providers within MSAs.

  Let me relate the need to oversee quality issues based on my past experience with another competitive bidding program. My company strives to manufacture high quality devices that meet the special needs of individual patients. We participated in a competitive bidding program that previously evaluated devices through a comprehensive review of device quality and features. Unfortunately, that program now focuses solely on cost savings for this category of devices. The quality of the devices is no longer assessed. Now I'm concerned patients' needs aren't being met.

- **Required Bidding Process for Expansion.** We have strong concerns about CMS' ability to use bid amounts determined in setting payments in one MSA to set rates in another 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.

- **Small/Rural MSA Exemption.** Many are concerned that small and rural MSAs would not have enough suppliers who would be able to provide for the entire MSA, or network to provide for the entire MSA, to meet patient needs. We recommend that small and rural MSAs be exempted from this program.

- **Public Meeting on Categories/Codes.** Product codes used by CMS are too broad and inconsistent to adequately describe products with diverse and broad ranges of quality, functionality, technology, and clinical utility. Beneficiaries may not have access to a full range of products if the accepted bidding amount does not reflect the varying costs of the range of products. Also, we believe it was most unfortunate that CMS found it necessary to make changes in the product categories even while the bidding process was underway, rather than having done so beforehand. This could have been avoided if stakeholders had been given the opportunity to comment on product categories and codes in advance.

  We urge CMS to allow for such public comment on the categories and codes being bid and such potential problems. Furthermore, to make public the list product categories to be bid in each future bidding cycle and the codes proposed for each product category. CMS should

then convene a meeting of the PAOC to discuss the categories and codes and accept written comments, which must be taken into account in making final determinations. CMS should also be required to provide a rationale for final determinations and respond to comments received.

- **Savings Certification**. Many are concerned that the focus of the competitive acquisition program is financial savings with little consideration of the impact on quality of care and patient choice. If CMS expands the program to additional MSAs, the agency should have to certify a net savings per category to the DME fee schedule of over 10%. The net savings must include accurate deduction for administrative costs associated with the program. We note that in CMS' Final Report to Congress: Evaluation of Medicare's Competitive Bidding for DMEPOS in 2004, the report stated that "the project saved significant expenditures, nearly 20 percent overall in each site." Thus, a 10% net savings requirement should be reasonable.

- **Grandfather Enteral Nutrition Patients.** There are provisions in the program currently to "grandfather" patients who receive DMEPOS items for which payment is made on a rental basis, thus allowing them to maintain current services for the duration of the rental contract. These grandfathered products require frequent and substantial servicing, and the grandfathering policy applies to capped rental items, like oxygen. However, enteral nutrition patients, who are fed via a pump, are not included in this grandfathering process. These patients are frail and elderly – often stroke patients – who have been receiving their pump and enteral nutrition supplies for long periods of time and have developed trusting relationships with a particular supplier. We believe that these rental contracts should also be honored and grandfathered as well since enteral nutrition pumps are covered under the prosthetic device benefit and meet the criteria outlined for exemption.

- **Antitrust Protection for Potential Competitive Bidding Networks.** To ensure that small suppliers are able to form networks and participate in the program, we recommend that the Department of Justice provide limited antitrust immunity be accorded to DMEPOS suppliers that meet the regulatory criteria be given.

- **Appeals.** The adoption of this new program is complex, and its initial steps have been met with some difficulty. To ensure fairness and transparency, we recommend that CMS provide written explanations/remedies for providers whose application for participation was rejected due to technical reasons (i.e.: non-bid price related issues).

Conclusion

Thank you again for holding this important hearing. As an industry that thrives from innovation and relies upon the energy of its significant small manufacturers, we greatly appreciate the opportunity to raise awareness of the concerns about the impact of the new competitive acquisition program on Medicare and their access to innovative products. We look forward to working with this Committee on ways to ensure all manufactures remain able to offer existing quality product and develop new and innovative DME for this critical sector of the population.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Testimony of:

Jose F. Navarro, RPh

Navarro Discount Pharmacies
Medley, Florida

To:

United States House of Representatives
Committee on Small Business
Subcommittee on Investigations and Oversight

On:

Competitive Bidding for Durable Medical Equipment: Will Small Suppliers be able to Compete?

Wednesday, October 31, 2007

INTRODUCTION

Chairman Altmire, Ranking Member Gohmert, and Members of the Subcommittee, my name is Jose F. Navarro and I am a member of the Board of Directors of Navarro Discount Pharmacies, which operates 20 pharmacies in Florida. I am also a member of the National Association of Chain Drug Stores' (NACDS) Board of Directors. NACDS represents chain pharmacies with stores numbering from four to over 6,000. Regardless of their size, all NACDS members are deeply concerned about the impact of the competitive acquisition program on patient access.

Thank you for the opportunity to share our thoughts and concerns about the impact of the competitive acquisition program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) on small businesses. The DMEPOS competitive acquisition program was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Currently, the program, which is limited to 10 metropolitan statistical areas (MSAs), including Miami, where 19 of our pharmacies are located, includes bidding for ten categories of medical equipment and supplies.

Durable medical equipment includes such items as diabetic testing supplies and monitors, walkers, hospital beds, wheel chairs and oxygen tents. 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 diabetes 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 healthcare provider in the community for the Medicare beneficiary. One-on-one patient-pharmacist consultations often provide the first opportunity to identify chronic illnesses, 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. Continued participation of pharmacies in serving Medicare patients should therefore be an important consideration in the DMEPOS competitive acquisition program.

However, some of the provisions of the competitive acquisition program and other rules proposed by the Centers for Medicare and Medicaid Services (CMS) for DMEPOS suppliers will prevent pharmacies from effectively serving their Medicare patients. We offer our thoughts to help the Subcommittee address certain flaws in the competitive acquisition program. First, the competitive acquisition program's requirement for supplier accreditation creates significant administrative and financial burdens on small pharmacies. Second, diabetes testing supplies sold at retail pharmacies should not be subject to the competitive acquisition program. Third, the expansion of the program to establish national or regional competitive bidding areas for mail-

[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.

order suppliers could limit participation by small pharmacies and reduce patient access to needed DMEPOS supplies and services. Fourth, CMS' proposed $65,000 surety bond requirement, layered onto the already onerous requirements of the competitive acquisition program, could make it even more difficult for small pharmacies to continue serving Medicare patients' DMEPOS needs.

SUGGESTIONS TO IMPROVE DMEPOS COMPETITIVE ACQUISITION PROGRAM

State-licensed retail pharmacies should be exempt from the accreditation requirement.

The competitive acquisition program requires suppliers to be accredited before they are awarded a contract. The goal of this requirement is to reduce fraud, waste and abuse in the Medicare program. While we stand with CMS in eliminating fraud, waste and abuse from the Medicare program, we do not believe that requiring the accreditation of state-licensed pharmacies will accomplish this goal. CMS has at its disposal a variety of tools to ensure integrity in the Medicare program; however, accreditation of state-licensed pharmacies, as required by the competitive acquisition program, is an unnecessary requirement that could threaten patients' access to DMEPOS supplies from their most accessible provider.

While requiring accreditation of pharmacies is unlikely to reduce fraud, waste and abuse, it may have the result of reducing the number of pharmacies that are available to supply durable medical equipment and supplies to Medicare beneficiaries. The cost 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 to participate in the program. Pharmacies already struggle to minimize operational expenses to remain competitive in the marketplace, and are skeptical of the accreditation process because even if they undergo the accreditation process, they have no guarantees that they will ultimately be allowed to participate in the DMEPOS program.

In the regulatory impact statement issued with the DMEPOS competitive acquisition final rule, CMS estimated that approximately 15,973 bidding suppliers would participate in the first round, of which 9,584 (about 60 percent) would be awarded a contract.[2] However, at a recent Program Advisory and Oversight Committee meeting, CMS stated that only about 2,200 locations have applied for accreditation.[3] It is important to note that this number represents actual locations and not individual companies that have applied to become accredited for the first round. The expenses and onerous requirements related to the accreditation process are likely largely to blame for the lack of a robust bidder pool in the first round.

[2] Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 72 Fed. Reg. 18081 (April 10, 2007).
[3] Program Advisory and Oversight Committee Meeting, October 11, 2007, Baltimore, Maryland.

In response to concerns raised by small suppliers, CMS has stated that small suppliers will have an opportunity to participate in the competitive acquisition program by creating a small supplier target.[4] However, given that only 2200 suppliers applied for accreditation for the first round, it is reasonable to expect that the number of retail pharmacies that are ultimately awarded contracts for any product category could be very low. As a result, Medicare beneficiaries could face tremendous disruptions in their care as small pharmacies that were unable to cope with the accreditation costs or were not awarded contracts are forced to stop serving Medicare patients.

Further, accreditation, as required of state-licensed pharmacies, is superfluous. 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 evaluation of their operations and compliance programs related to pertinent 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 regulations. Today's pharmacists are highly educated, licensed experts in the use of medications and medical devices who advise patients and healthcare providers. These pharmacists are ideally situated to provide Medicare patients using diabetes 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.

Diabetes testing supplies sold at retail pharmacies should not be subject to competitive acquisition.

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 a 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.[5] Other private and public healthcare 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 acquisition on diabetes supplies during the competitive bidding demonstration projects. Thus, expansion of the competitive acquisition program to diabetes supplies sold at retail pharmacies will create

[4] Note 2 at 18044.
[5] Pharmacy Times, *The Ashville Project: A Special Report* (October, 1998), *available at* http://www.pharmacytimes.com/files/articlefiles/TheAshevilleProject.pdf.

significant confusion and frustration to diabetic patients and their providers. At a time when Medicare is attempting to move away from fragmented care, competitive acquisition is likely to interfere with patient access and could adversely affect diabetes management.

Further, the study conducted by HealthPolicy R&D examined issues related to competitive acquisition 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 acquisition 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.

CMS should not create national or regional competitive acquisition areas for mail-order items.

In the competitive acquisition final regulation, CMS stated that, for the year 2010 and thereafter, it has the authority to establish national or regional competitive acquisition areas for suppliers that furnish items through mail-order. As I have already shared with the Committee, 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 proper use of the DMEPOS items with their pharmacist. This individualized attention is critical to increasing patient compliance with therapy regimen and improving health outcomes, particularly with chronic disease such as diabetes. 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.

Creation of a regional or national mail-order program may produce an additional disincentive for small providers to participate in the program as the contracts are likely to be awarded on the basis of price alone. As a result, patients may find it even more difficult to gain access to the community pharmacist they trust, eroding the benefits of the pharmacist-patient relationship shown to improve health outcomes and reduce healthcare spending.

State-licensed retail pharmacies should be exempt from CMS' proposed surety bond rule.

During the midst of competitive acquisition program implementation, CMS also proposed to require a $65,000 surety bond from all Medicare DMEPOS suppliers. As if the costs associated with accreditation and bidding did not create enough disincentives for small suppliers, CMS' proposal to require a surety bond is likely to keep many interested suppliers from participating.

In its proposal, CMS estimated that annual administrative costs related to the surety bond would be $2000.[6] For many DMEPOS suppliers, the administrative fees required in obtaining the surety bond could be prohibitive as such fees may not be recouped even through their total annual Medicare billing. Ultimately, small DMEPOS suppliers, particularly those serving rural and underserved areas, may be unable to cope with the recurring and rising administrative costs in providing DMEPOS services and may be forced to turn away Medicare beneficiaries.

According to CMS' own calculation, up to 15,000 DMEPOS suppliers currently enrolled in Medicare (22 percent of whom are in rural areas) could cease providing items to Medicare beneficiaries as a result of the surety bond.[7] CMS envisions that, "most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail-order order or via the World Wide Web)."[8] Clearly, CMS indicated that this proposed rule will result in even fewer small pharmacies participating in the Medicare DMEPOS program. As a result, patients could face tremendous difficulties in obtaining their necessary DMEPOS items and services.

CONCLUSION

I am grateful for the opportunity to testify before you today. Thank you for providing a forum to air our concerns about the DMEPOS competitive acquisition program. If sufficient protections are not offered for retail pharmacies and their patients, Medicare beneficiary access to DMEPOS items and pharmacy assistance in using those items will be reduced, and Medicare Part B spending will likely increase.

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[6] Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 72 Fed. Reg. 42007 (August 1, 2007).
[7] *Id* at 42008.
[8] *Id.*

Written Statement of the Food Marketing Institute

Submitted to the

HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

"COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT: WILL SMALL SUPPLIERS BE ABLE TO COMPETE?"

OCTOBER 31, 2007

Your Neighborhood Supermarkets

The Food Marketing Institute (FMI) would like to thank the Subcommittee on Investigations and Oversight for holding this important hearing on the structure of the competitive acquisition program for Durable Medical Equipment, Orthotics and Supplies (DMEPOS). We believe that the program is being implemented in ways that could be harmful to small businesses and to the Medicare beneficiaries these businesses serve. FMI offers the following comments about the DMEPOS program, focusing particularly on the burden of the program on small business as well as the importance of retail access to diabetic testing supplies.

FMI is an association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion – three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

Supermarket Pharmacies have an Important Role in the Health and Wellness of Consumers

FMI's retail members also operate over 19,000 in-store pharmacy departments. FMI estimates that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, the association anticipates that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

Supermarket pharmacies have a unique ability to focus on health care issues in a holistic way. By providing healthy foods, pharmacy access and other on-site health care services, FMI's supermarket pharmacy members meet the health and wellness needs of their customers. In addition to wholesome foods, preventative health items and prescription medications, many of these stores offer durable medical equipment to Medicare beneficiaries, diabetic testing supplies in particular.

The Impact of Competitive Bidding for DMEPOS on Small Businesses

When it mandated that competitive bidding for DMEPOS be implemented, the Congress ordered the agency to consider the impact of the program on small businesses, and to provide special protections for these businesses. FMI does not believe that the CMS protections for small businesses are adequate. The program CMS has designed will produce in most cases perhaps one or two small business suppliers per category in each competitive bidding region. The expenses of accreditation and even the bid process itself will be prohibitive for many small businesses, and a number of the programs CMS is considering (such as the national or regional mail-order program

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for diabetic testing supplies) seem designed to raise the bar against small business entry to the DMEPOS marketplace even higher. The subcommittee will hear important testimony today about the impact of the DMEPOS competitive bidding program on small businesses, and FMI—which represents supermarket and mass-merchant companies from the very small to the very large—wishes to echo these concerns.

The Importance of Retail Access to Diabetic Testing Supplies

FMI was encouraged earlier this year when CMS decided that diabetic testing supplies sold in a retail setting would not be included in the first round of competitive bidding. While these supplies will be subject to competitive bidding in the ten competitive bidding areas when delivered via mail-order, Medicare beneficiaries in these areas will still be able to acquire supplies at retail store if they wish. FMI believes that it is particularly important for Medicare beneficiaries to have continued access to diabetic testing supplies through the retail pharmacies of their choice. The CMS decision to restrict competitive bidding to mail-order is an important step in preserving this access. Furthermore, because Medicare beneficiaries tend to form relationships with individual pharmacies, which can contribute to positive health outcomes for Medicare beneficiaries, FMI believes that it is important for beneficiaries with diabetes to be able to maintain these relationships with their local pharmacy. The policy to limit competitive bidding to mail-order for diabetic testing supplies should be permanent. A competitive bidding program which results in only one or two suppliers in a region providing diabetic testing supplies would prevent many, and perhaps a significant majority of Medicare beneficiaries, from receiving diabetic testing supplies in their chosen retail pharmacies. Accordingly, FMI would urge the subcommittee to encourage CMS to adopt policies which maintain full retail access nationwide as the agency continues to implement competitive bidding.

FMI was particularly concerned by language in the CMS proposed rule implementing competitive bidding suggesting that the agency was considering the potential for "mail only" access to diabetic testing supplies under a national or regional competitive bidding program beginning in 2010. While the agency appeared to back away from this language in its final rule, FMI would urge the subcommittee to carefully oversee the implementation of a national or regional competitive bidding program to ensure that beneficiaries continue to have access to diabetic testing supplies through their neighborhood pharmacies.

Furthermore, FMI believes that any proposed national or regional mail-order program will be of special concern to the subcommittee, since such a program would by definition tend to favor larger businesses.

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Accreditation Issues for Retail Pharmacies

One requirement facing entities wishing to participate in the competitive bidding program is a costly accreditation process. While accreditation will eventually be required of all Medicare suppliers, so far CMS has only set a deadline for suppliers participating in the first round of competitive bidding.

Our members' recent experiences in considering whether to participate in the first phase of the DME competitive bidding program have highlighted the prohibitively expensive and unnecessary accreditation requirements that CMS is imposing on retail pharmacies, first under the competitive bidding program and later as a part of Medicare supplier quality standards. We believe that these requirements could affect Medicare beneficiaries' access to certain categories of DME, particularly diabetic testing supplies.

FMI strongly supports the efforts of Congress and CMS to ensure that Medicare beneficiaries receive quality DME products and services that are not tainted by fraud and abuse. We believe that the quality standards that apply to DME suppliers are important and that a reasonable accreditation system is a sensible way to ensure that these standards are met. However, the current accreditation requirements being applied to retail pharmacies are duplicative and unreasonable. In order to meet the accreditation standards, retail pharmacies are required to undergo extensive site visits and accredit every store in their chains, regardless of whether that store provides DME. The costs of accreditation are especially egregious when compared to the marginal added value of the accreditation. The accreditation requirement duplicates the requirements of state licensure and other government program requirements that apply to licensed pharmacies and thus produces little, if any, extra information for CMS to use in determining whether the pharmacies will meet the "basic good business practices" reflected in the standards.

The accreditation requirements include documentation of appropriate financial, human resource, and information management; evidence of product safety measures; and standards for product preparation and delivery, and beneficiary education. But these requirements simply duplicate requirements that pharmacies must meet to maintain their state pharmacy and Drug Enforcement Agency licenses and to participate in other Medicare programs, such as Part D. For instance, the accreditation process requires that pharmacies be licensed, maintain complex record keeping systems to track activity, customer history and dispensing activity, and operate under the Board of Pharmacy, DEA and other health agency rules and regulations. All of these requirements must be met in order for a pharmacy to receive a state license. Likewise, the DMEPOS accreditation requirement that personnel be licensed matches state licensure requirements that all pharmacists be licensed in the state in which they are practicing.

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Given the high cost of accreditation and the marginal benefit that accreditation brings, FMI urges Congress and CMS to modify the accreditation standards for pharmacies. FMI strongly believes that CMS has the authority and discretion under Section 1834(a) (20) (A) of the Social Security Act, and Section 302(a) (1) of the Medicare Modernization Act of 2003, to exempt licensed pharmacies from the DMEPOS accreditation requirements. However, CMS has stated that it does not agree with our interpretation of these laws.

Therefore, FMI believes that a clarification of the quality standards to exempt pharmacies and licensed healthcare providers is appropriate. FMI has also proposed a compromise to CMS that will continue to promote the aims of the accreditation requirements, namely ensuring quality health care services for Medicare beneficiaries, while reducing some of the accreditation cost burden on licensed pharmacies. FMI has proposed that all suppliers, including pharmacies, continue to be accredited by a CMS-deemed accrediting organization. However, for licensed health care providers, such as pharmacies, the accreditation standards would be modified so that a smaller sample of store locations would be required to undergo site visits, essentially to confirm the work that has already been done by pharmacy licensure organizations. If the accrediting organization finds that the accrediting standards are not being met, a larger sample of stores would then be subject to site visits. Additionally, only those stores that would provide DME items would be required to be accredited. This compromise would allow CMS to ensure that the accrediting standards are met and that Medicare beneficiaries receive quality health care services and products. It also relieves some of the financial burden that accreditation brings, particularly to small businesses.

Conclusion

FMI thanks the subcommittee for holding this important hearing. We are hopeful that Congress and CMS can design a competitive bidding program that provides better protection for DMEPOS suppliers that are small businesses. The current program will undoubtedly reduce the number of small businesses among the ranks of DMEPOS suppliers—both in its general design and through the workings of accreditation requirements that are unnecessarily onerous, particularly for pharmacies and other licensed health care providers.

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Statement for the Record
National Association for the Support of Long Term Care (NASL)
Competitive Bidding for Durable Medical Equipment:
Will Small Suppliers Be Able to Compete?
House Committee on Small Business
Subcommittee on Investigations and Oversight
October 31, 2007

The National Association for the Support of Long Term Care (NASL) is pleased to present this statement for the record in connection with the Small Business Committee's November 1, 2007 hearing on the Medicare competitive acquisition program for Part B items and services.

NASL is a national trade association representing providers of ancillary products and services to the long-term care and home care industries. Our member companies provide medical equipment, as well as therapy services, diagnostic services, software systems, and other ancillary services, to those care settings.

The focus of this hearing is the new competitive bidding program for medical equipment, prosthetics, orthotics, and supplies (DMEPOS), created by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)(Public Law 108-173). The Centers for Medicare and Medicaid Services (CMS) in the Department of Health and Human Services (HHS) issued final regulations in April of this year implementing the program. The first phase of the program will begin in 2008 in ten of the largest metropolitan statistical areas (MSAs) in the country. The program will be expanded to eighty MSAs in 2009 and to additional areas after 2009.

Our comments on this program may be summarized as follows: CMS made an important and ultimately far-reaching decision in its final rule. Despite the fact that Congress's clear intent and the entire legislative debate on the competitive acquisition provisions of the MMA were focused on home care, CMS decided to include the nation's long term care (LTC) facilities ("LTC" or "nursing facilities") in the new program, and to do so in the very first phase of the largely untested program. In particular, this will affect the provision of enteral nutrition (tube feeding for patients who cannot take food orally and/or digest and absorb adequate nutrition from traditional nutrient sources), the product area where there would be the biggest impact on LTC facilities in the first phase of the competitive bidding program.

NASL supports fully the Congressional goals of promoting high-quality care for Medicare beneficiaries while achieving improved management of costs. However, we are concerned that application of this program to DMEPOS provided to patients in LTC settings will not only fail to meet these goals, but will unfairly disadvantage small suppliers that have special expertise in supplying these necessary items to LTC patients and thereby compromise patient care.

The Competitive Bidding Program Presently Cannot Address the Unique Challenges of Providing Medical Equipment and Services to Patients in Long Term Care Facilities

NASL appreciates this opportunity to explain to the Committee the unique challenges of providing medical equipment and supplies, in particular enteral nutrition, in the nursing facility setting. We are concerned that the competitive bidding structure cannot adequately address these differences, especially at the very outset of the program before CMS can gain needed experience in implementing competitive bidding. As a result, there may well be a disruption in quality care provided to fragile patients in nursing facilities and a significant burden needlessly placed on nursing facilities and small suppliers.

Most Part B items and services within the scope of the competitive bidding program are provided in a home care setting by suppliers who focus on the home care market and may not have the familiarity or expertise to service residents of a nursing facility. As a result, the program was developed based on a home care model, which generally involves a distribution process designed for beneficiaries who are mobile and not institutionalized. However, the clinical needs of patients using enteral products in LTC facilities, how these products are distributed in the LTC setting, and the particular quality standards applicable to nursing facilities are quite distinct from the home care setting.

LTC Facility Patients Have Special Needs

Residents in LTC facilities are usually older and more impaired than home care patients, often admitted after an acute care stay or unsuccessful home stay, and require a different regimen of care. For example, more than 80 percent of all enteral patients residing in LTC facilities require an enteral pump for safe delivery of nutrition, while less than half of all enteral patients residing in their home have such a need. LTC facility residents often have multiple clinical conditions, significant physical limitations, and the need for assistance with activities of daily living. In short, they often require a range of services beyond enteral nutrition.

LTC Facilities Have Special Relationships With Patients and Third-Party Suppliers

LTC facilities have a special relationship with their residents. These facilities assume responsibility for coordinating the work of an array of clinicians, providers and suppliers to meet residents' healthcare needs. Indeed, LTC facilities are subject to federal requirements mandating that "each resident must receive and the facility must provide the necessary care and service to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. Part 483.

Items furnished to LTC facility residents typically are furnished by either the facility itself or by highly specialized suppliers working in a close clinical relationship with the facility's nursing personnel. The level of clinical management and services related to the furnishing of DMEPOS to patients in institutionalized settings is substantially higher than that for non-institutionalized patients. In fact, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) publishes separate Standards for Tube Feeding for the home care versus nursing facility setting. As a result, LTC facilities working with third-party suppliers traditionally have established long-

standing relationships with selected suppliers based on experience, trust and respect for their level of professionalism. We believe it is critical that these facilities continue to have the ability to select a supplier that meets performance and service criteria necessary for the needs of their patients. The competitive acquisition program could force nursing facilities to use unfamiliar suppliers and potentially interrupt ongoing relationships and established and functioning care plans that have worked to the benefit of their residents.

Finally, the new Medicare Part B quality standards that facilities must meet to bid were developed with a focus on homebound and home health care patients, and do not reflect the types of requirements necessary for services provided in a LTC care facility. For example, CMS would newly require an additional accreditation process through JCAHO. While very few long-term care facilities are accredited by JCAHO, they are already bound by strict federal and state institutional quality oversight that is enforced through conditions of participation with Medicare and Medicaid programs and through survey and certification requirements. To add an additional layer of oversight for such facilities would be costly and an administrative burden that would not result in improved quality. A single set of accreditation standards for all suppliers in the program is impractical and costly.

Applying the Competitive Bidding Program to Products Supplied to LTC Patients Will Not Fulfill the Purposes of the Program

The use of competitive bidding to set prices and pay for therapies provided primarily in a LTC setting has not been tested sufficiently or successfully. CMS previously conducted a DMEPOS competitive bidding demonstration to test the feasibility and the program impacts of using competitive bidding to set prices for DMEPOS. CMS included only one therapy in the demonstration where the majority of patients are in a setting other than the home (i.e., enteral nutrition). The agency ultimately removed enteral nutrition from the first demonstration project and concluded it was not well suited for competitive acquisition in its final report to Congress, due to the complexity of the nursing home setting. Importantly, there was no conclusive evidence that competitive bidding would produce any clinical benefits for residents of nursing facilities.

There is Precedent for Treating the Long Term Care Setting Differently Under Medicare

There is precedent for treating the coverage and payments of items and services provided to residents in LTC facilities differently than those provided to other beneficiaries—namely, in the Part D prescription drug benefit. CMS' regulations implementing this benefit artfully distinguish between providing drugs to the general Medicare population and providing those same drugs to Medicare beneficiaries in a LTC facility, subjecting pharmacies that serve LTC facilities to different quality and performance criteria than other pharmacies and providing distinct payments. According to CMS, providing drugs to LTC residents requires "special attention to ensure the unique needs of the vulnerable population are met without compromising the quality of pharmaceutical care." *Issue Paper #26, High-Quality Access to Long Term Care Pharmacies* (Jan. 21, 2005). Until now, CMS has consistently recognized the unique needs of nursing facility residents in receiving covered benefits under Medicare law.

Many Suppliers Affected by the Application of the Competitive Bidding Program to LTC Facilities are Small Suppliers who would be Disproportionately Disadvantaged

A meaningful percentage of current suppliers to nursing homes are small suppliers with specialized expertise in the LTC setting and that often provide only one or a few categories of products. These suppliers are at an inherent disadvantage in the competitive bidding process that threatens their economic livelihood and will lead to consolidation and an increased presence of larger suppliers. CMS' final rule implementing the competitive bidding program attempts to address this problem, but ultimately does not offer an effective method of leveling the competitive paying field. AdvaMed, the world's largest medical technology trade association, estimated that CMS' earlier proposed version of the rule (which is not substantially different from the final version in this area) would cause approximately 8,500 small suppliers in the first ten competitive bidding areas to lose all Medicare DMEPOS business—likely putting these suppliers out of business altogether.

Under the competitive bidding program, a small supplier that has in the past specialized in providing products to LTC facilities is required to provide products to all beneficiaries in a competitive bidding area to participate. These small suppliers will be competing for the first time with much larger companies that have generally focused on the homecare market, requiring expansions in the type of products supplied and in geographic service areas. Larger suppliers with larger volumes, established homecare care businesses and larger service areas have a clear advantage in this program. In addition, small suppliers to LTC facilities will be disadvantaged in the following ways:

- The methodology used to arrive at the "pivotal bid" that will set the cut-off for winning bids will lead to fewer and larger winners.

- Because the contract price will be below the bid price for some successful bidders, this introduces a significant financial risk that will be more difficult for smaller suppliers to accept.

- This could leave nursing facilities in a potentially precarious position. LTC facilities have an obligation to be responsive to clinical needs in a very timely manner. However, under the competitive bidding program, LTC facilities would be restricted in contracting with the most appropriate suppliers to help manage the patient's total care needs, including DMEPOS, drugs, and medical and ancillary services.

- The competitive bidding program easily could disrupt LTC facilities' current contracts with third-party suppliers, particularly exclusive contracts with one supplier for all medical supply products for all patients, if the supplier does not win a contract. This will create inefficiencies and increase administrative burdens for these facilities.

CMS Did Not Adequately Address the Needs of Small Suppliers.

CMS attempted to assist small providers in the final rule by allowing them to form networks if they cannot service the entire competitive bidding area independently. However, this

"opportunity" would actually create an additional challenge for small suppliers who will already be hard-pressed to shoulder the burdens of competitive bidding. The building of a network is no easy feat, requiring a high degree of collaboration with competitors under stressful and unique circumstances, and must be done somehow without implicating the antitrust laws. Assuming that a network can be structured to meet the scrutiny of the Department of Justice (DOJ) and the Federal Trade Commission (FTC) regarding antitrust concerns, the majority of small businesses may not have the business or financial resources for network-building, and will face the additional risk of expensive antitrust litigation with disappointed suppliers regardless of the DOJ and FTC views.

How Congress Can Help

NASL and several other organizations have raised the concerns outlined above with CMS in detailed comments responding to the proposed rule to implement the competitive bidding program. Unfortunately, CMS did not effectively address to any of these concerns in finalizing the rule. We ask that Congress act to limit this competitive bidding program to those services where it makes sense and to exempt nursing facilities.

This exemption would be consistent with congressional intent and the plain language of the Social Security Act (SSA) creating the competitive bidding program. LTC facilities already purchase DMEPOS through what is essentially a private competitive bidding process. There is nothing to suggest that Congress intended to undermine institutional purchasing power or replace the current private system with a public system.

We seek your support for legislation to exempt the inclusion of nursing homes in the competitive bidding program, or at least to delay implementation of competitive bidding in this setting until 2009, so that these critical issues are resolved and both vulnerable beneficiaries and the small, specialized suppliers that serve them are protected.

For further information, please contact Peter C. Clendenin, Executive Vice President, NASL, at (703) 549-8500.

TESTIMONY OF

Randall G. Pence, Esq.
Capitol Hill Advocates, Inc.
representing Compressus, Inc.

FOR

Subcommittee on Investigations and Oversight

United States House of Representatives

REGARDING

"Competitive Bidding for Durable Medical Equipment: Will Small Suppliers Be Able to Compete?"

October 31, 2007

Mr. Chairman, good morning. I am Randall G. Pence, Esq. of Capitol Hill Advocates, Inc., representing Compressus, Inc. I appreciate this opportunity to share my views with regard to health care delivery issues of great importance to the country and which your hearing is investigating today.

Mr. Chairman, I would like to commend you for holding this hearing. Your leadership, and that of Chairwoman Velazquez, will help shine a light on growing problems influencing the ability of the nation to provide state-of-the-art health care to its citizens to meet the needs of a growing and aging population that will stretch our resources to the limits.

This is an issue that has many branches. I would like the opportunity to discuss one of those branches today, set forth the issues and suggest a course of action for the committee.

One of the areas in which we can expect tremendous challenges in a core medical specialty will be in medical imaging. The relationship of the medical imaging community to small business interests will be many and varied. Many radiology businesses, clinics, imaging centers and related businesses are themselves small businesses that will play an important role in the timely and dependable delivery of health care services in any location in the country. Any medical care issue, and its related costs, affects the costs and quality of life for small businesses and their employees that are served by local medical service providers, doctors, clinics and more. This committee has already done great work examining the impact of the explosion of health care costs, and rising health care premiums, for employer-provided health insurance to small business employees.

One of the greatest challenges that the medical imaging community faces is a shortage of radiologists to meet increasing demands. The health care community must find a way to make the most effective, efficient and reliable use of the existing manpower and equipment in order to handle more images with relatively fewer resources.

We need to understand while as the population grows, and health care demands further mushroom to serve the graying baby-boomer generation, the number of qualified, experienced radiologists is not growing to meet the demand. In fact, we have a serious shortage of radiologists in America now. As the population grows and ages, we should expect an exponential increase in the number of medical image "reads" that will be required from the inadequate number of qualified experienced radiologists available to our healthcare system.

Advanced systems need to be able to integrate diagnostic images with the associated patient records, to make sure that imaging and other medical data is readily available and readable at a variety of patient care and diagnostic locations, including hospitals, doctors' offices, separate radiology clinics, and even on laptops.

This has important medical policy consequences. The lack of interoperability between existing information systems from different vendors is the most critical problem facing the health care profession today.

In order to provide best use of resources, most efficiently and economically, the radiology community will need to adopt comprehensive technology solutions that provide seamless integration of disparate information systems and provide users the freedom to select best of breed PACS, HIS/RIS, EMS and CIS tools.

Many Members of the Subcommittee will appreciate the special relevance of this issue in the context of rural health care, health care in tribal centers for Native Americans, small town health centers and remote areas of the country, even for those areas that have some local access to radiologists. Certain radiological specialties in diagnostics for intricate problems involving the brain, the heart, hand and foot imaging and others, may only be available by linking local imaging facilities with radiology centers that work with in these highly specialized fields of medicine. The ability to reliably access such diagnostic specialties from afar can bring assurance to patients and their medical care providers that although they may

be located in geographically remote locations, in the case of highly specialized radiology diagnostics, their resources are equal to that enjoyed by their urban cousins.

Replacing the equipment is not a solution, but there is a practical solution to this problem.

A preferable approach for the health care industry is to move toward a far less expensive approach that would rely upon software solutions that allow the country to continue to use existing hardware in addition to other upgrades as may occur as needed: compatibility via an affordable software solution that neutralizes the incompatibility factor.

Advanced Radiology Consultants, S.C. of Illinois (ARC) is a leader in this field. Dr. John Anastos, President of ARC, has summed up the challenge to America's medical imaging industry: "As the number of images captured for diagnostic review increases exponentially, the need for radiological services is outpacing the growth of the radiologist workforce, so the ability to improve productivity and workflow is critical."

We may be seeing a breakthrough in software that will provide a good, workable technological solution, a comprehensive software solution that can bring seamless, ubiquitous interoperability at a fraction of the cost of replacing machines. It is a tremendously innovative solution that is just emerging onto the scene and which should come to the full attention of health care policy-makers.

Compressus has developed a private sector, off-the-shelf software technology that answers these challenges.

This advanced technology solution emphasizes the electronic collection and distribution of digital imaging data including: digital storage and transmission of imaging data, diagnostic workstations for efficient interpretation by radiologists, automated voice dictation for generation of reports and electronic and secure distribution via the web of images and reports to referring physicians. It addresses the lack of communications inherent to traditional PACS implementations based on proprietary technologies and competitive pressures, which often forces medical facilities to settle for a sub-par solution with a single vendor providing all components or rely on stop gap measures to achieve common communications across all operational areas – many times in the form of moving personnel to follow the images from one workstation to another. The system acts as a communications hub, enabling various PACS, HIS, RIS and other data information systems to connect and communicate across the enterprise.

To maximize productivity and reduce spikes in workload, physicians have the ability to access patients work lists throughout to network.

Efficiency and managing time used is essential. Dr. Anastos has said the new system "will not only help us shorten the time from which a patient is scanned to the time when a completed report is delivered to a referring physician, this solution emphasizes enhanced distribution and sharing of digital images and data throughout the diagnostic and reporting process."

He has also said that the technology "will transform the way medicine is practiced here in Chicago, the United States, and around the world."

Mr. Chairman, I am pleased to work with Compressus and would be happy to provide information to the committee and staff to expand on how the breakthrough MEDxConnect technology can help meet the needs being discussed today.

There are a number of actions that the House Small Business Committee could take to bring these challenges into focus for examination and correction by the affected parties.

I would urge the committee to consider holding a hearing on this matter early in 2008 or as the schedule will allow to examine the need for an efficient and interoperable medical imaging infrastructure.

In preparation for such a hearing, it would be advisable to solicit the views of major participants in the medical imaging industry, including radiologists, hospital systems, clinics and major hardware vendors whose outlook would be helpful to the committee, especially for its impact on the small businesses in the industry.

Clearly, the issues raised above also have close impact to other constituencies of great importance to Members of the Committee. This must be a matter of crucial importance to rural health care constituencies who will depend on remote medicine, telemedicine and distant diagnostic support to give them health care as good as their urban friends. The use of advanced technologies to link rural hospitals, clinics and health care agencies to imaging diagnostic resources across the world rapidly and reliably will be one means to provide rural citizens with services that rival any in the world. The same may be said for health care facilities serving Native Americans and military personnel who have unique medical needs though they may be distant from major medical facilities. Further, this will provide better health care services, and help control spiraling health care costs, which we know will have a very significant impact on every aspect of small business.

Mr. Chairman, thank you for this opportunity to submit testimony. I look forward to working with you and your staff to bring oversight to this vital issue. Thank you for your leadership.

THE ORTHOTIC AND
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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 INVESTIGATIONS AND OVERSIGHT

Hearing on "Competitive Bidding for Durable Medical Equipment: Will Small Suppliers Be Able to Compete?"

Wednesday, October 31, 2007
Room 2360, Rayburn House Office Building

Chairman Altmire 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 is grateful to this Subcommittee for holding today's hearing to examine the impact of the impending competitive bidding program for durable medical equipment, off-the-shelf orthotics and supplies provided under the Medicare program. Members of the O&P Alliance have expressed serious concern to both Congress and the Centers for Medicare and Medicaid Services ("CMS") on the issue in the past and we continue to have strong reservations about implementation of this program. Our primary concern revolves around the impact that a system based on the lowest price, rather than highest quality and patient care, will have on beneficiaries and suppliers.

I. The O&P Profession Objects to the Inclusion of Prosthetic and Orthotic Services in the Competitive Bidding Program

Initially, the competitive bidding program will include ten (10) product categories under the durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") benefit. CMS will expand the program to include additional items after 2009 and will designate items included in the competitive bidding program through program instructions or other means, without issuing new formal regulations.

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, but primarily because O&P professional care is highly clinical and service oriented, not commodity-based like most of durable medical equipment and supplies. The level of education, skill, and experience necessary for practitioners to provide comprehensive O&P care differs dramatically from the supply of DME. Some basic orthotics, known as "off-the-shelf" orthotics, were included in the competitive bidding program by statute and could be subject to competitive bidding as early as 2009, but these orthotics are not included in the initial round of competitive bidding.

As stated throughout the comment and implementation period for the competitive bidding regulations, the orthotics and prosthetics profession is opposed to the inclusion of *any* orthotic or prosthetic items and services in the Medicare competitive bidding program. As the Subcommittee is aware, 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. As already stated, the provision of prosthetics and orthotics require varying degrees of clinical intervention and expertise in order to be properly fit the patient. Even the more basic types of orthotic devices cannot always be safely and appropriately utilized by the patient. The relationship the patient forms with the prosthetics or orthotics clinician is similar to that of a patient's relationship with his or her physician. Channeling prosthetic and orthotic patients to the lowest bidder is counter to the way quality orthotic and prosthetic care is best delivered.

The O&P Alliance also believes that access to care will be adversely affected by competitive bidding. Fewer available facilities in which to obtain such care will necessitate more travel for the patient. Orthoses and prostheses are typically fit to persons with a disability or orthopedic impairment. Requiring this population to travel further, especially as they frequently require aid with transportation, would be a mistake. Moreover there are occasions when beneficiaries will require off-the-shelf and non-off-the-shelf orthoses 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 for orthotics and prosthetics because this system 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.

II. The O&P Profession Supports Quality Standards for Prosthetic and Orthotic Services

Congress recognized the concerns about maintaining quality in a system that is based on the lowest bidder but mandating that all Medicare DMEPOS suppliers, not only those that participate in competitive bidding, satisfy certain quality standards. However, the competitive bidding final rule does not finalize in regulation these DMEPOS quality standards, and CMS reserves the right to change the standards by program instruction or methods that do not involve public notice and comment.

The O&P Alliance whole-heartedly supports the implementation of strong quality standards for all categories of DMEPOS, including specific standards for orthotics and prosthetics. An important aspect of ensuring compliance with these quality standards is through the use of facility accreditation administered through qualified, private accrediting organizations. The O&P Alliance has been disappointed to date with CMS's efforts to ensure that the quality standards for O&P care are strong enough, and that the

accrediting organizations selected to accredit O&P suppliers have sufficient experience with the O&P profession and the provision of quality orthotic and prosthetic care.

In addition, there currently is no firm date by which DMEPOS suppliers must be accredited in order to be reimbursed by the Medicare program. The O&P Alliance believes that this represents a disservice to not only the supplier community and accreditation agencies but more importantly, to Medicare beneficiaries. CMS is missing an opportunity to simultaneously ensure access to quality care, diminish fraud and abuse, and protect program dollars by implementing, by a date certain, the accreditation requirement as part of the DMEPOS quality standards.

If a significant number of DMEPOS suppliers that are unwilling or unable to meet accreditation standards choose to no longer be Medicare suppliers, it can be assumed that the bulk of accredited DMEPOS suppliers remaining are qualified, legitimate, and much less likely to fall within the subset of suppliers who are submitting fraudulent claims. While requiring accreditation is certainly not a fool-proof way to stop Medicare fraud and abuse, it can have a significant impact on the number of suppliers billing fraudulently. An effective framework is already in place. Setting a reasonable date for compliance can only bring positive results.

We are also concerned that CMS and its contractors are not prepared to enforce DMEPOS supplier accreditation at the most basic level: claims payment and processing. It is not enough to require accreditation, and to screen enrolling and reenrolling suppliers to ensure that they are accredited. Accreditation status must also be edited at the claims processing level, when DMEPOS claims are presented for payment. How can the accreditation requirement be considered effective if there is no mechanism in place to prevent an accredited home oxygen supplier from providing diabetic footwear, or a pharmacy from providing an artificial limb, or a breast prosthesis supplier from providing a child with spina bifida with a spinal orthosis?

CMS must ensure that its contractors use their claims processing computer systems to match the types of claims and codes submitted with the supplier type and specific accreditation; otherwise accreditation is irrelevant. In the short term, this lack of claims processing edits will undermine the effectiveness of the competitive bidding concept. In the long term, the lack of claims processing edits opens the door to abusive suppliers and fails to protect the Medicare beneficiary against unqualified suppliers.

Thank you for this opportunity to submit our statement for the record. If we can be of further assistance, please contact Peter Thomas at (202) 872-6730.