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

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS
UNITED STATES
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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SUBCOMMITTEE ON RURAL DEVELOPMENT, ENTREPRENEURSHIP AND TRADE
HEARING ON:
THE IMPACT OF COMPETITIVE BIDDING ON SMALL BUSINESSES IN THE DURABLE MEDICAL EQUIPMENT COMMUNITY

Wednesday, February 11, 2009

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

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 2360 Rayburn House Office Building, Hon. Heath Shuler [chairman of the Subcommittee] presiding.

Present: Representatives Shuler, Luetkemeyer, and Thompson.

Also Present: Representatives Altmire and Klein.

Chairman SHULER. I call this hearing to order. Good policy is defined by basic philosophy that governs good medicine. First, do no harm. That principle seems simple. And, yet, there are incidents in which well-meaning legislation has unintended and sometimes devastating consequences.

This was the case in 2007 when the CMS established competitive bidding for durable medical equipment. When it was first launched, competitive bidding was expected to save up to one billion dollars in taxpayer money.

The idea was that it would drive down the prices by increasing competition and creating more choices, but this was not the case. Instead, it devastated small suppliers of rural communities.

Although Congress intervened and stopped the competitive bidding, CMS used the last days of the Bush administration to push it through. Fortunately, the new administration has put a hold on that eleventh hour rule.

In the next two months, the administration will review and hopefully eliminate the competitive bidding program altogether. This morning I will explore the efforts of competitive bidding on small healthcare providers and discuss the importance of ending the program entirely.

The vast majority of the durable medical equipment providers are small businesses. Most of them deliver highly specialized products, which require a depth of industry knowledge. But competitive bidding allows many of the small suppliers to be outbid by larger, less knowledgeable firms.

By nature, this process gives the upper hand to larger suppliers, who can churn out several medical devices and span an entire bidding area.

In the last year, the Committee has held hearings to review the effects of competitive bidding on entrepreneurs. Time and again our witnesses have said the exact same thing. The program hurts small businesses and cripples rural communities.

Because Medicare payments total a large percentage of the revenues for small suppliers, the effects of the program were devastating for those that failed to win contracts. This was particularly true for durable medical equipment suppliers in rural areas.

If those firms are forced to shut their doors, the entire community will suffer, both economically and in terms of access to care. Although the name would suggest otherwise, competitive bidding did nothing to encourage competition. If anything, it worked to suppress it.

In the long run, the program would have caused choices to dwindle and prices to go up. We need to continue to work to ensure that small businesses are able to compete in the market.

I look forward to today's testimony. And I thank the witnesses for their participation. Before I turn it over to the Ranking Member, I also want to thank the staff in such short notice and right out of the gate for holding a hearing so early in the 111th Congress. They did an outstanding job. To Michael Day and to the entire staff and for all that you guys have continued to do, I appreciate all of your hard work and what you provide for all of the members, both the majority and the minority and to both sides, what great work you do.

At this time I would like to yield to my Ranking Member, Mr. Luetkemeyer, for his opening statement.

Mr. LUETKEMEYER. Thank you, Mr. Chairman. I would also like to echo my thanks to the staff. I know they were in my office yesterday afternoon late and still managed to get me a briefing book with everything in it, the testimony, their initiative, and their abilities.

Thank you, Mr. Chairman, for holding another hearing on the important topic of ensuring that our senior citizens have access to the best available durable medical equipment supplies and services, as offered by small businesses.

The House Small Business Committee and this subcommittee recognize that small business is critical to the economic health of this country. The competition provided by small businesses ensures lower prices, greater supplies, higher quality, and increased innovation.

Rural America presents unique issues with respect to providing healthcare services to residents. Distances are vast. Population density is low. And healthcare providers are few.

More importantly, small businesses play an important, irreplaceable role in providing healthcare services in rural areas. Without a robust small business sector, the ability of other business to provide quality healthcare to the employees would falter. The result would be a diminishing of the economic well-being of rural areas because employees will not locate in areas where they cannot get adequate healthcare.

Policies must ensure that all Americans, wherever they live, have access to the highest quality of healthcare, whether that is a service of surgeons or suppliers of slings for patients.

In 2003, Congress mandated that the Centers for Medicare & Medicaid Services, or CMS, institute competitive bidding for the provision of durable medical equipment supplies.

The implementation of this program has raised significant concerns with small businesses. In fact, the concerns were so serious that Congress acted to delay implementation of the bidding program that was to go into effect on July 1, 2008. On January 16th, 2009, in response to the actions of the 110th Congress, CMS issued some new rules on the implementation of competitive bidding.

I am very interested in hearing from the suppliers represented here today whether concerns that led the Congress to action last July have been ameliorated by subsequent administrative decisions by CMS.

If those concerns have not been allayed, then I am interested in hearing what potential problems will exist for the small businesses that are involved in providing durable medical equipment supplies and equipment to America's senior citizens.

Finally, I am interested in hearing what improvements can be made to the competitive bidding that reduce any adverse consequences on small business. I think it is important that Congress have the information necessary to act if CMS adopts a procedure that forecloses numerous small businesses from participating in the competitive bidding process.

Without small business, the competitive bidding program will not lead to lower prices, greater supply, and increased innovative in the durable medical equipment marketplace.

With that, I yield back, Mr. Chairman.

Chairman SHULER. Thank you, sir.

Our first panel, obviously we have Mr. Laurence Wilson. Mr. Wilson is currently the Director of the Chronic Care Policy Group in the CMS' Center for Medicare Management. As the director, he is responsible for Medicare policy on a broad range of fee for service healthcare benefits. He is also responsible for administrating the agency's process for the coding of drugs, devices, and other items and services. Mr. Wilson has worked for CMS since 1988.

Mr. Wilson, thank you for being here today. And we look forward to hearing your testimony.

Mr. WILSON. Thank you, Mr. Chairman.

STATEMENT OF LAWRENCE WILSON

Mr. WILSON. Good morning, Chairman Shuler, Ranking Member Luetkemeyer. I am pleased to be here today to discuss the durable medical equipment, prosthetics, orthotics, and supplies competitive bidding program.

This important initiative, required under the Medicare Modernization Act of 2003, has three key components: quality standards and accreditation, financial standards, and competitive bidding. Together these will help 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.

The Centers for Medicare & Medicaid Services, or CMS, implemented the program on July 1, 2008 in 10 metropolitan areas around the country. After two weeks of operation, the program was

delayed by the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA.

CMS is now preparing to move forward with that program in 2009, as the law requires. And we look forward to incorporating the improvements mandated by MIPPA as well as others being planned by CMS to ensure a smooth transition to the new program for both beneficiaries and suppliers.

As the 2008 implementation showed, the accreditation program and use of financial standards provides important safeguards for beneficiaries and the Medicare program. These safeguards support good quality and customer service, act to weed out illegitimate suppliers, and ensure a level playing field for suppliers competing for contracts under the program.

I would note that with the support of suppliers, CMS will be implementing the quality standards and accreditation process on a national basis this year.

CMS conducted a wide variety of activities to involve stakeholders in the development of these standards. Some, such as special focus groups, were targeted specifically to small suppliers.

CMS has also adopted a number of approaches to ensure small suppliers have the opportunity to be considered for participation in the competitive bidding program. First, CMS worked in collaboration with the Small Business Administration to develop new, more representative definition of small suppliers. CMS then designed policies linked to this definition to help small suppliers.

For example, our final regulations allow small suppliers to band together in networks in order to meet certain program requirements. The regulation also employs a formula to ensure that multiple contract suppliers are selected for each product category in an area. More importantly, the regulation establishes a special 30 percent target for small suppliers in the program.

CMS was pleased that of the 335 contract suppliers selected in 2008, 64 percent met this definition of small supplier. Our 2008 experience demonstrated that competitive bidding has the potential to bring value to Medicare beneficiaries and taxpayers. In fact, average savings across the ten metropolitan areas was 26 percent.

As a specific example, in Pittsburgh, the price of a standard wheelchair dropped 32 percent under this program. That savings would have gone directly to Medicare, the taxpayers, and to beneficiaries in terms of lower co-insurance.

While this program offers real benefits, we do understand that it will be difficult for some suppliers because the law requires that there be both winning and losing bidders and the new system represents a significant change in how suppliers operate under Medicare.

We will continue to work closely with suppliers, manufacturers, beneficiaries, and others to make improvements in the program as we move forward. For example, MIPPA requires a number of important changes to the program.

Just a few of these include: a document review process to assist providers or suppliers in completing their bids; an exemption to the competitive bidding program for certain items provided by hospitals; exemption from the program for rural areas and for small metropolitan areas in future rounds of bidding that is beyond this

next first round; establishment of a competitive bidding program ombudsman to address supplier and beneficiary concerns.

Last month, CMS issued an interim final rule with comment period to implement these and other provisions of MIPPA. Yesterday, CMS issued a notice seeking comment on a contemplated 60-day delay in the effective date of that rule.

CMS, itself, is also considering additional improvements to the program. These include an improved online bidding system, streamlined financial documentation requirements, earlier education for suppliers on the bidding process, and many other features that we intend to improve.

We have also established new membership of our program advisory and oversight committee to advise CMS as it implements the program. This group is equipped to advise CMS on a broad range of issues and has experience with on-the-ground operational issues, including the critical interaction between beneficiaries and suppliers.

In conclusion, beneficiaries deserve quality items and services at a lower price from reliable suppliers. CMS is committed to the secuessful implementation of this program in order to deliver that.

Once decisions are made about the timing of implementation, CMS will notify the public and begin to educate suppliers and beneficiaries about the program.

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

[The statement of Mr. Wilson is included in the appendix in page 39.]

Chairman SHULER. Thank you, Mr. Wilson. The Ranking Member and I will have several questions. We may ping-pong back and forth on these. Thank you for your time again.

You know, the latest ruling didn't reflect any significant changes as we reviewed. CMS has until the end of 2009 to fix its problems. Wouldn't it be better to just start over and start with a much better process?

I mean, we have seen from numerous newspaper articles. We have seen from numerous suppliers and providers that the programs that go into effect are going to have this disastrous impact on small business.

Isn't there a way that we can delay this until the end of 2009, instead of just, you know, as most times when bad policy goes here in Washington, we try to cram it down all the small businesses and all the suppliers? And ultimately it is going to end up hurting and having a negative impact. And the quality of care will obviously go down.

I mean, isn't there a way that we can just halt and assist this until the end of 2009 so we can get good legislation put together?

Mr. WILSON. I thank you, Mr. Chairman. Let me start by answering your question with respect to the rule. We did publish a rule at the end of last year or in January. The importance of that rule is to codify the specific changes that Congress asked us to make in our regulations that would put us in a position to implement the program, as the law requires, this year.

Really, what the law requires this year is that we open the bid window, begin the competition in 2009. So we feel like we are merely codifying those changes to put ourselves in a position to implement the law.

We do understand, of course, that suppliers have had concerns with this program and will continue to have concerns with this program. This is a program that has many benefits for beneficiaries in terms of lower co-insurance, benefits to taxpayers and Medicare in terms of reduced expenditures under the Medicare program.

As we all know, sustainability of the Medicare program is a key issue, both for the administration, Congress, and others. So, we do feel that this does offer benefits that will help with sustainability of Medicare.

In the end, we do believe that we can implement the program in a way that allows small suppliers to participate in the program that will result in a number of them being included in the program. In the 2008 process, 64 percent of the winning contract suppliers were small suppliers under our definition. And we think that was a good result but, again, do understand the concerns, sir.

Chairman SHULER. Why wouldn't we have a proposed rule, instead of a final rule? Why wouldn't we have a proposed rule? We could get more of the people who are actually involved in this process actually having a voice, as opposed to, to be quite frank, just some of the past administration?

Mr. WILSON. Well, I think for a couple of reasons. One, we did go through a notice and comment rulemaking on this provision. We did have numerous public forums. We had approximately eight advisory committee meetings. They were public. We took public testimony. We took comments on the quality standards, had over 5,000 comments, made important changes in the quality standards, made important changes in the rule.

I think we have been very transparent with respect to the rules through our Web sites, listserv announcements, all of the different phone calls we have had, whether they are bidder conferences, access to staff in terms of meetings, briefings that we have held.

I think that at the end of the day, we have a set of policies that allow us to implement this program consistent with the law. I think that the law in MIPPA asked us to make some specific changes in that and move forward in 2009. That is what we are trying to do right now.

I am not sure that revisiting issues that we have dealt with in the past will necessarily change a lot, particularly in round one, given that we have tried to address those issues in a transparent way.

Chairman SHULER. Give me one example of those changes, significant changes, that have been made that would impact someone who lives, oh, let's say in Murphy, North Carolina, who are two and a half hours from Atlanta, two and a half hours from Knoxville, two and a half hours from Asheville, North Carolina. So, I mean, they are really, you know, in a very rural area.

Mr. WILSON. Well, one thing I could say, sir, is that under the provisions in MIPPA, rural areas are excluded from competitive bidding and metropolitan areas that have populations of less than 250,000 people. So competitive bidding has not occurred in those

areas, will not under round one of competitive bidding, the round one rebidding required by MIPPA, and will never apply there in the future.

I think that is a significant change. Under the Medicare Modernization Act, we did have the authority to apply competitive bidding there. And we don't—

Chairman SHULER. So there is really no use saying that there is a round two. Is that what you are alluding to?

Mr. WILSON. Well, there will be a round two of competitive bidding. The law requires that there be a round two. And there may very well be future rounds. They will never occur in a rural area because the law prohibits us from doing that.

Chairman SHULER. What about these providers that are eligible in, let's say, Texas but they can actually go across states and that they have no business in, say, North Carolina? How can they? Especially at this point in time and the way the economy is, for providers from other states to come into my home state and take business away from the people, the hard-working people, that have had a relationship—and I think that is the most important thing to remember is a relationship with these patients. Why is that possible? I mean, that doesn't make good business sense in these economic times.

Mr. WILSON. Sure. What I would say is that in the Medicare program now, competitive bidding aside and for the last, you know, 40, almost 50 years of existence of the program, we have not had restrictions on businesses going into new areas and expanding.

Many businesses do that all of the time, whether there is a competitive bidding program or not. They expand, go into new areas, and try to provide services to customers. So we do see that as something that has naturally occurred.

That said, we understand that that was a concern in the first round of bidding last year. We did hear that quite a bit and hear some concerns about suppliers that were either new to an area, had no experience in an area, or new to a particular product category. Maybe they never provided oxygen before, let alone provided oxygen in Chattanooga.

Chairman SHULER. And that is probably one of the biggest problems that we would have, is providers coming in who are not even educated in the field.

Mr. WILSON. Right. And so I think a few things that the program does now—

Chairman SHULER. So that change has been addressed?

Mr. WILSON. Well, I will say that it has been addressed in some ways. And let me just say that we do have accreditation requirements. There are higher-level accreditation requirements and quality requirements on oxygen suppliers. So they do have to meet a set of standards.

We do ensure that all suppliers that participate in the competitive bidding program meet financial standards as well so they have the wherewithal to provide services on a consistent basis to beneficiaries, but we do not at this time have restrictions on movement. We want to make sure that they have licenses in the appropriate states and in the appropriate areas to provide those services.

We will do that. But, at this time, we don't have a policy that prevents that type of natural business expansion into a new area or a new product category.

Chairman SHULER. I think that gets back to my point. You know, when you look at the financial wherewithal, that starts to really make it more difficult on small businesses, what I would consider the mom and pop shops that have been so helpful in our communities.

I mean, I have a close friend of mine that provides services that go far and beyond what he gets paid for. It is just because of his relationship with his patients that they have had and conducted. And he feels a moral obligation to be able to provide for these people.

And so it is going to be very difficult for small businesses to engage if they don't have the financial wherewithal, especially during struggling times and more difficult.

Obviously I know that we have to make sure that the businesses are structured properly and they do have the financial wherewithal so they stay in business so they can provide a service.

Can you educate me on what financial wherewithal would be? Is it a million-dollar net worth? Is it half a million dollars net worth in company value?

Mr. WILSON. We rely on a set of financial standards that look at things like credit reports, look at past tax records, make sure that they have appropriate cash flow and resources in order to maintain/sustain a business.

I think you raised some very good points, sir. One of the things I would say, you know, about local businesses is that we did see a number of businesses that won bids in new areas.

One of the things they did to provide those services was subcontract with local suppliers. So maybe those local suppliers didn't win under competitive bidding, but they were allowed to participate in the program through subcontracting arrangements. So I think that is a good thing.

The other thing that we saw is that many suppliers and many patients made use of a provision in the law which allows certain suppliers to grandfather. So maybe you are a patient in a certain area and you have a relationship with a supplier. If that supplier did not win under competitive bidding, you can choose to maintain that relationship for a service like oxygen, for example, regardless of whether or not that supplier won.

So we did see those types of things occur, which sort of allowed the transition to the new program to be seamless and allowed suppliers to sort of maintain that local relationship with a patient.

Chairman SHULER. I think that is going to be the extreme. I think, you know, when someone wins a bid, they are going to walk in and say, "I am your new provider. They are going to walk the walk, and they are going to talk the talk about how well they are doing in their business. And now I am going to be your new provider."

I doubt, very frankly, that the patients are going to know that this grandfathered clause is actually in effect. There are not enough marketing dollars that are being spent to know that you can be grandfathered in.

When that happens, you know, it would be great because I think a lot of our small businesses obviously would stay in business. But if you are only grandfathering in 20 percent of your overall business, you are probably not going to stay in business.

Mr. WILSON. In response, sir, what I would say is that when we implemented the program in 2008, as you said, we did see a lot of the new suppliers, the winning suppliers, were aggressive in terms of trying to get patients, trying to get business. That is why they bid. That is why they bid and tried to win.

We also did see—and we checked because one of the key things that we wanted to do as part of our monitoring program was to make sure that oxygen patients continued to get oxygen because it is not like a hospital bed, where if a patient needs a hospital, maybe they can wait a day or an hour. Oxygen you need every few seconds.

We did check. Many did grandfather because they did want to keep that relationship with the patients, at least for a while. And I think that was important for patients and important for their suppliers.

But I do understand the issue and the concern. Thank you.

Chairman SHULER. I would like to yield to the Ranking Member now for his questions.

Mr. LUETKEMEYER. Thank you, Mr. Chairman.

Who is driving this bidding process issue?

Mr. WILSON. The law is driving the bidding process. The law requires that this competitive bidding process is in place.

Mr. LUETKEMEYER. Who drove the law initially? What group? Was there a group of people, a part of the industry? Was there an issue, a problem? Any time you have a change, do something like this, something or somebody or some group is driving it. Who was driving it?

Mr. WILSON. Yes. I am not sure of the group. I sort of doubt it was the industry.

[Laughter.]

Mr. LUETKEMEYER. I kind of doubt that, too. This is an awfully large group here this morning. We had a meeting the other day on some stimulus package stuff, and we didn't have this many people in here for that. I think that probably is an overriding issue over this, but this is something that obviously has gotten some folks stirred up.

Mr. WILSON. Well, I can tell you this, sir. I don't know what particular group drove this or where this came about in terms of negotiations over the managed Medicare Modernization Act. I mean, I wasn't involved in those discussions. I am a career person, as I think you know.

The thing that I will say is that there has been interest from CMS and formerly HCFA before that, the GAO, the OIG, and others on trying to get better pricing in this area of the program. There has been a lot of work done that shows that the pricing is excessive and that there may be a better way to get prices through the competitive bidding program.

In earlier legislation; that is, prior to the Medicare Modernization Act, there was a demonstration that did test this in two areas: Polk County and San Antonio, Polk County, Florida and San Anto-

nio, Texas. So there was work done on this prior to the national program.

I think the interest was in better pricing because better pricing results in not just lower expenditures for Medicare. It results in lower expenditures for beneficiaries. Beneficiaries paid 20 percent coinsurance.

So, under my example, from Pittsburgh, a 32 percent savings on a standard power wheelchair equates to about $279 in savings. That is important for beneficiaries, particularly in times now where beneficiaries have been hit pretty hard in the pocketbook in terms of their 401(k)'s and in terms of their retirement plans.

And so I think there has been interest from the beneficiary area and the consumer groups, certainly interest from those around town here, like the GAO, Office of Inspector General, and CMS, that are interested in having fair prices.

I know that is a long-winded answer, but I think that—

Mr. LUETKEMEYER. That is normal for Washington.

[Laughter.]

Mr. LUETKEMEYER. I am just curious. I know that you made a comment a minute ago about the service portion of this. To me, it would seem that service is a big part of the, or should be a big part of the bid here. How do you factor that in? I think I have some information, but I want to be sure that it is a part of your thought process when you accept the bid.

Mr. WILSON. It absolutely is. And when you look at Medicare's quality standards—and, of course, all suppliers in order to compete under competitive bidding must meet the quality standards. And, indeed, later this year every supplier in the country will have to meet the quality standards and be accredited.

They talk about not just the equipment but delivering the equipment, setting up the equipment, educating the beneficiary on its use, and being there to provide customer service.

So that it is very much factored in as part of the covered benefit. And the issue is, I think, what is the price for that and the equipment.

Mr. LUETKEMEYER. During your answer to one of the Chairman's questions, you made a couple of comments with regards to grandfathering in some of the providers. How long can you extend that to those folks to continue to be grandfathered in the program or are they grandfathered forever or just for a few months, a year or two, or where do we go with that?

Mr. WILSON. Well, if the supplier and if the patient agree to maintain their relationship for a service like oxygen, then they can continue that relationship for as long as the patient and the supplier want it.

For new patients, that grandfathering does not come into play. It is just for existing patients. So it would extend forever, although most patients are on oxygen for, I think the average is, about ten months under Medicare.

Mr. LUETKEMEYER. Okay. Obviously there are some concerns about what we are doing here. You are in the middle of this. What would you see or what would you like to see or what would you prefer done to alleviate the problem or get to the goal of containing costs, yet allowing competition or allowing great service? If you

were in our position here to try and find a balance here, what would you suggest be done?

Mr. WILSON. Yes. Difficult to answer that. Difficult to answer that question. You know, I am looking at--right now I work within sort of the boundaries of existing law and think about proposals for changes to the extent that there are changes being considered.

You know, I think there are certain elements in Medicare that are pretty important. You know, you want to maintain quality and access and you want to pay well. When you don't pay accurately, you incentivize fraud. You incentivize bad behavior. And you bring in bad actors.

And so I think we need to try to get to a way to pay accurately for these services. And we need a set of quality standards that we have today that ensures that people coming into the program and acting as suppliers are those that are prepared and able to provide quality services and deliver quality items.

I was very pleased to see that part of AAHomecare's initiative on fraud was to try to boost the quality standards. We have quality standards for this area of the program. Their thought was to make them more rigid.

So we are very interested in hearing those ideas because I think when you elevate quality in these kinds of programs, provide accurate pricing, you get pretty good results.

Mr. LUETKEMEYER. Okay. Thank you. Thank you, Mr. Chairman.

Chairman SHULER. I just have a couple of more questions. Talk to me about the companies that were involved in the original demonstration. Talk to me. How successful have they been? I mean, have they made a pretty good business structure since the original demonstration? Polk County I think you said. San Antonio?

Mr. WILSON. San Antonio, sir.

Chairman SHULER. How are those companies doing?

Mr. WILSON. I would have to get back to you on that. I do not recall which particular companies were involved in the demonstration. So I would not be able to tell you where they are now.

The thing that I can tell you about the demonstration is that our findings were that we saved about, in the neighborhood of, 20 percent. I think it was a little less than that in terms of program savings. And that was savings for Medicare and beneficiaries in terms of reduced coinsurance and that we didn't see any impact on quality.

Those were the findings of the demonstration. And, again, I am not sure where those companies are now and what their history has been. I would be happy to check, though.

Chairman SHULER. Yes because I guess it was our understanding that a few of those companies aren't doing very well at all.

We talked about the cost savings. And, obviously, being a blue dog member of that caucus, I am very much for cost savings. You talked about the 20 percent now. What increase, if any, of quality of care did you find out in this survey research?

Mr. WILSON. In the demonstration?

Chairman SHULER. Yes.

Mr. WILSON. The finding that I recall from the evaluation report on that demonstration was that quality was not negatively impacted. That is what I recall.

So I don't know that quality increased as a result of the demonstration. The thing that I would say is there were not quality standards in place and an accreditation process in place at the time. There was also not a set of financial standards, as the law requires us to have now, and a number of other programmatic requirements.

Chairman SHULER. Obviously we can cut savings in a lot of different areas. I mean, obviously we have a budget that is coming up that I think probably no one is going to be happy with. I mean, there are going to be probably broad cuts across the board. But in these financial times, we obviously have to cut costs. But we always have to be very mindful of the quality of care.

I have a grandmother who is on oxygen. And I know her quality of life actually increased once the doctor recommended her to be on oxygen. Now, obviously this is for another discussion. That is no different than insulin medication for patients. I personally feel that it is a prescription. And as long as the person is alive and needs oxygen, then it needs to be provided for them, just as insulin is.

My grandmother was not a smoker. I mean, it is just happenstance. That is how God made her.

I guess help me to understand. If a patient is distraught with the service that they were getting provided by the company that has been awarded the contract, what can they do about changing to get another provider? How would that process work?

Mr. WILSON. Under the competitive bidding program, sir?

Chairman SHULER. Yes.

Mr. WILSON. Well, I think one of the things that we found—and I will just go back to our 2008 experience. And let me just first preface this by saying that the program was only active for two weeks. We call it 14 days in July. So we don't have a lot of experience or a lot of records on everything.

Chairman SHULER. Obviously some research has been done before. I mean, like most laws, surely, we think this process through before we throw it into law.

Mr. WILSON. Absolutely. And I think one of the things that—I think there are a lot of things, as I mentioned in my testimony, that we want to try to improve in this program for next time.

But one of the things that I think we did a pretty good job on was getting in touch with beneficiaries, talking to them about the program, making sure that Medicare 1-(800) knew what to do, having an infrastructure in place, caseworkers, ombudsmen staff at our contractors to be able to address concerns that came up from beneficiaries.

So I think we did that pretty well. And so what would happen if someone had a concern with their supplier or maybe there was confusion about grandfathering and we didn't see a lot of this, but when we did, we were able to get a caseworker on these issues and usually resolve it within 24 hours.

Typically what would happen, most of the calls that we got did involve "I need a supplier for this, and I don't know where to go because the supplier that I used to go to no longer is part of the competitive bidding program."

We were able to direct them to new suppliers. And in most cases, there were multiple suppliers. Actually, in all cases, there were multiple suppliers in each area to provide choice to beneficiaries.

We had, you know, 42-44 oxygen suppliers in Miami. Most places have 15 or 20 suppliers for a product category. Puerto Rico had fewer. That is not part of the program. Next time Congress excluded Puerto Rico.

So I think that was a process that worked for us and worked pretty well.

Chairman SHULER. Well, Mr. Wilson, just in closing, I would like to suggest if there is any way possible for CMS to scrap the program and start all over, I would highly suggest that.

And I would like to obviously work with my colleagues on Small Business and obviously with the other committees to try to work with getting through some better quality standards.

Obviously we need standards. We obviously need to cut costs. We need that, especially in the economic times that we are having. But to put our small businesses out is very difficult. We need to create jobs, not cut jobs and put people out of business.

You know, some of them, I'm sure there are a lot of people who are attending here today that probably have their mortgages attached to their businesses. I mean, there is a way that, as with most people, the biggest asset that they have is their home.

And so when you don't compete in the competitive bidding process—and I am sure if you look at the financial side of it, that that probably would be a negative toward a business if that is their source of the liability that they have. They don't have their house paid for. And that is where they put all of their debt of their company based upon an equity or have a line of credit for their company based upon their home equity loan.

So I think we obviously need to take a much better look at this and possibly start all over or take some of the information obviously that has been provided.

I mean, there are some things that can be done. I think there is a compromise at some point. And I want us to all compromise and work together. I mean, the reason why so many people showed up today that it is true and dear to their families and their livelihoods.

Big business pushes over the small business in a lot of areas. And I just don't think that it is going to help lower costs. It may in the short term, but I think in the overall long term, we are going to see more problems and issues when it comes to the large companies coming in and taking control of the smaller ones and putting these people out of business.

So I thank you for your comments, your testimony. Do you have any other questions?

[No response.]

Chairman SHULER. And we will try to very quickly change out and have our next panel. Mr. Wilson, thank you so much for your attendance. And thank you. Thanks for all of your hard work.

If the folks who are on the next panel would go ahead and grab a seat?

What a distinguished panel we have here. I would like to thank the panel for coming and spending their time here in Washington and giving their testimony.

Each of you will have five minutes to present your testimony. And there will be a little light. It goes green. And then yellow means that you have a minute left. And then it goes to red.

And then hopefully just try to finish up within the five-minute allotment time. We obviously have a very large panel here. We would like to get through all of the testimony and certainly the members be able to ask questions because I think it is so important that we may be preaching to the choir here, but I think as members, it is a great education for us. And that is why we hold these hearings for the members to educate them on the policy that may sound good and look good on paper, but examine the impact to our small businesses and to our people.

At this time I would like to yield to my good friend Mr. Altmire to introduce our first witness.

Mr. ALTMIRE. I thank the Chairman.

I do have the high honor of introducing not just a constituent but a very good friend, Georgie Blackburn, who is Vice President of Government Relations and Legislative Affairs for Blackburn's, a privately held home medical equipment and supplies provider in Tarentum, Pennsylvania.

She also serves as treasurer and board director for the American Association of Homecare. AAHomecare represents homecare providers, equipment manufacturers, and other organizations, operating in approximately 3,000 locations across all 50 states.

I would say, Mr. Chairman, that Ms. Blackburn and her business are good corporate citizens. They provide the highest-quality care. And they are exactly the model for what we are talking about here today with the impact small businesses can have on their local communities and why we need to keep them.

Thank you, Mr. Chairman.

Chairman SHULER. Thank you, sir.

Ms. Blackburn, you will be recognized for five minutes.

STATEMENT OF GEORGETTA BLACKBURN

Ms. BLACKBURN. Good morning, Mr. Chairman and distinguished members of the Subcommittee. I am pleased to be here today on behalf of the American Association for Homecare and should say that our members provide products in all 50 states. Members include providers and manufacturers of home medical equipment and services, prosthetics, orthotics, and medical supplies to Medicare beneficiaries in their homes.

I urge you to permanently suspend the bidding program. It will force the closure of thousands of small providers and reduce access to quality care for millions of Medicare beneficiaries.

Since the last hearing on this topic before this Subcommittee in May of 2008, Congress delayed the competitive bidding program for a period of 18 to 24 months and directed the Centers for Medicare and Medicaid Services to address the disastrous results from the first round of bidding. This was part of the Medicare Improvements for Patients and Providers Act of 2008.

CMS has made as few changes as possible under the law in order to issue a rule on the last day of the previous administration with no structural changes to a flawed program.

The interim rule is slated to go into effect on February 17th, 2009. The CMS deadline on the reissued final rule to solicit comments on a delay is tomorrow, February 12th, giving only six days to respond. And there has been no opportunity for any public comment or any evaluation of the problems that plagued round one throughout 2008.

Last year CMS disbanded the Medicare Program Advisory and Oversight Committee, which Congress mandated to advise CMS on the bidding program. Congress should exercise oversight of CMS, examine the process by which CMS issued the final rule, and urge the administration to rescind the rule.

HHS has the authority to suspend and review pending federal rules as detailed in the White House Chief of Staff memorandum of January 20th, 2009. We hope the Subcommittee will allow for more public scrutiny of this program.

Providers compete but we compete on quality and service. Medicare sets reimbursement rates. However, the CMS-designed bidding program is anti-competitive and fatally flawed. By selectively contracting with a small number of the homecare universe, it reduces competition because it eliminates 90 percent of the competitors.

This government-mandated consolidation of the marketplace will lead to significant job losses. It will force small providers out of business, often family businesses serving their communities for decades.

For the typical home medical equipment company, Medicare beneficiaries represent 40 to 50 percent of their customer base. Being shut out of Medicare for a three-year contract period will be a death knell for small providers.

CMS expects fewer than 400 companies to be contracted to provide services in the initial 9 bidding areas if rebid. Currently 4,127 companies serve those same 9 areas.

This program, whose primary selection criterion is lowest price, represents a race to the bottom. CMS frequently cited that the program was an anti-fraud mechanism. This is incorrect. The bid program is simply a payment mechanism.

Our association has zero tolerance for fraud. We have developed an aggressive 13-point plan to stop fraud and abuse within our sector. We are tired of reading about criminals who have easily acquired provider numbers and syphoned millions of dollars from the benefit.

CMS must press the national supplier clearinghouse, who grants Medicare billing numbers privileges, to stop fraud by identifying the bad players before they start to bill. And CMS must ensure that the national supplier clearinghouse fulfills this mandate.

Ending fraud makes more sense than the endless rounds of cuts to the home medical equipment sector, which only serves to punish good providers.

Round one of the bidding program produced disastrous results for patients and providers in all MSAs. Patient services were disrupted. The availability of fewer providers delayed hospital dis-

charges. That resulted in longer hospital stays, increasing costs to Medicare.

Many accredited providers that submitted bids were disqualified based on erroneous errors. Providers with no history of servicing a region or with no business operations in a bidding area were awarded contracts. Structural flaws in the bidding program caused small providers to submit bids for fear of losing their businesses.

I am from Pittsburgh. It is not a rural area. But let me tell you what happened in Pittsburgh. Out of 289 providers, roughly 60 unique companies were awarded contracts. Of over 265,000 eligible Medicare beneficiaries, 18,000-plus relied on oxygen therapy and only 22 companies were contracted to provide it.

Over 30,000 residents that required tube feeding to stay alive were forced to switch to one of only 10 providers. And 80 percent of longstanding experienced, accredited providers were totally excluded.

Homecare is the most cost-effective setting for health care. It is the slowest-growing and one of the smallest sectors of Medicare, representing about 1.6 percent of Medicare dollars. In 2007, spending increased by less than one percent.

At this time of economic hardship, it is imperative that small medical equipment providers remain in business. Congress must ensure that local economies will not suffer and that patient access to care remains intact.

Congress must permanently suspend the Medicare competitive bidding program for home medical equipment or there will be catastrophic effects to small business providers, their employees, and certainly the patients they serve.

Thank you.

[The statement of Ms. Blackburn is included in the appendix in page 53.]

Chairman SHULER. Ms. Blackburn, thank you so much for your testimony.

Our next witness is Robert Brant. Mr. Brant is the President of Accredited Medical Equipment Providers of America in Davie, Florida. I want to tell you that Debbie Wasserman Schultz, who obviously represents your area, has done a fabulous job. I spoke to her on the House floor and she has been very supportive of our small businesses, certainly in the State of Florida and around our country. So, Mr. Brant, you are very well-represented there.

Mr. Brant, you will be recognized for five minutes.

Mr. BRANT. Thank you, Mr. Congressman.

STATEMENT OF ROBERT BRANT

Mr. BRANT. Chairman and Committee, thank you for allowing me to discuss Medicare's competitive bidding program and the negative effects it has for patients and equipment providers.

My name is Robert Brant. I am co-owner of City Medical Services in North Miami Beach, Florida. We are a 12-year-old company. We have been Joint Commission-accredited since 2000. We have seven full-time employees, and most have been with me for over five years. And they do enjoy a healthcare benefit.

I am currently President of the Accredited Medical Equipment Providers of America. We were formed shortly after the bid results

came out, mostly from bid winners and bid losers from Miami, Orlando, and Dallas MSAs, all opposed to the competitive bidding program.

The goals of the competitive bidding program were to reduce Medicare reimbursement and to responsibly minimize the number of providers for CMS to manage without limiting patients' access to care.

The fact is, in the last ten years, with the passage of new rules and regulations, all of the goals that once justified competitive bidding have already been achieved. The industry has negotiated a 9.5 percent cut to providers, and CMS withheld a 5 percent CPI increase, which both began on January 1st.

Despite that good news, Medicare released interim final rules on January 16th of this year in order to restart the program, using the same methodologies and techniques to award contracts without any financial accountability, allowing unlicensed, out-of-state, out-of-area bid winners, with no history of providing bid equipment throughout the first nine MSAs.

In fact, it was in a similar Small Business Committee hearing to this that Congressmen Altmire and Gohmert said that it did not meet Regulatory Flexibility Act requirements six months before bid winners were announced.

This program was based on a flawed demonstration project, with only a few categories that most winners viewed as acceptable loss leaders. Half the bid winners from round one of the project found the loss unacceptable as they did not participate in the second round.

Medicare noted key findings in an evaluation report of the demonstration project: one, a non-demonstration supplier acquired two demonstration suppliers; and, two, the parent companies of one demonstration supplier filed for bankruptcy. And another demonstration supplier also filed for bankruptcy protection.

Regarding the first ten MSAs, the ability to purchase bid winners has led to part of the disaster that followed. In Orlando, 14 of the 39 bid winners were over 100 miles outside of the area, without any means to service oxygen patients.

For any companies out of the area, it is a no-lose situation. Out-of-area providers place any low bid. And if they win, they think they may have a commodity that someone else may willing to buy, like in the demonstration project.

The interim final rule does not require a provider to even provide a bond to cover the bid. You don't even have to have a subcontract agreement in place to cover a 12-county area as large as the Dallas MSA before you bid. Then if you win the bid and cannot fulfill the contract, you can walk away without penalty. However, the low price is locked in for everyone else.

The Florida Department of Health certified that 9 of the 44 bid winners for oxygen were unlicensed. Our association was informed of this discrepancy when providers contacted manufacturer representatives of oxygen asking, "How do you get an oxygen license?"

This begs the question, how can a company place an accurate bid if they have never provided the service before? How can legitimate providers compete when bidders do not base bids on reality of providing service or equipment?

I made a decision years ago to compete in the industry by providing more costly systems, like liquid oxygen. In order to bid on oxygen, I had to submit the number of liquid patients I have taken care of. This is another determining factor that was ignored. Manufacturer representatives told us that some oxygen suppliers after winning the bid inquired about how to purchase liquid oxygen as well.

A liquid oxygen system is five times the cost of a standard oxygen system, but it is paid at the same reimbursement rate. It also has to be refilled every month. And that refill cost is in there as well. We had to buy a truck with a lift gate to carry the 110-pound reservoir every month to the patient. All of these factors would be in the company's ability to place a bid that they could honor without going out of business.

When the program was briefly implemented in the two weeks of July, physicians and hospital case managers pleaded with us to continue to accept payments. Discharge planners went through the published lists of bid winners, could not find a company that could provide liquid oxygen or respiratory therapists to set up their patients that they were accustomed to. They were accustomed to patient training and setup within a few hours, not within a few days.

This problem was exacerbated by providers refusing to address issues unless their orders were in addition to more expensive reimbursable items.

The reduction in companies that currently provide service is astounding. In the Miami MSA, which covers the 3 largest counties, 402 power mobility device providers were reduced to 18. More tragically is in the Miami MSA, 501 providers were reduced to only 44. In Hurricane Wilma, my company was without power for seven days.

In areas of Dallas, where they had 285 providers reduced to—I'm sorry. In the Dallas MSA's 12 counties, there were 4 counties that did not have a bid winner for oxygen in them. One of the counties, Rockwall County, does not even have a hospital in it.

President Obama said that he does not want to keep government programs that do not work and intends to expand on programs that do. At less than ten percent of Medicare's budget, durable medical equipment is the most cost effective program in healthcare. Our services keep patients out of hospitals and rehab centers so they can live independently in their homes.

During this economic crisis we do not want to needlessly close companies, causing more bankruptcies; burden the system with additional unemployment, which will end healthcare benefits; ruin an important community resource called upon during natural disasters; and, most importantly, limit a patient's access to care.

Thank you very much.

[The statement of Mr. Brant is included in the appendix in page 62.]

Chairman SHULER. Thank you, Mr. Brant.

At this time I would like to yield to the gentleman from Florida, Mr. Klein, to introduce our next witness.

Mr. KLEIN. Thank you, Mr. Chairman and Ranking Member Luetkemeyer. I appreciate the opportunity to be with you. And

thank you for holding this hearing. This is an issue that affects our patients in Florida and all over the country.

I know most of us are concerned, as you are for calling this, and the balance of making sure that the program is cost-effective, but we also have the quality and delivery of the product to the consumer in the most effective way. And that certainly was a failure of the CMS procedure that went forward a number of months ago.

Mr. Chairman, I have the distinct privilege of introducing a good friend and tireless medical advocate in our community on behalf of his profession and on behalf of the patients in our area.

Dr. Alan Routman is a practicing orthopedic surgeon in Fort Lauderdale, Florida. He has a very distinguished academic career. After establishing a practice in South Florida, he became one of the most respected voices in healthcare in our community, served as past president of the Florida Orthopaedic Society and the Broward County Medical Association, and earned the reputation of being a pragmatic and judicious expert on a variety of healthcare issues.

He is testifying today on behalf of the American Association of Orthopaedic Surgeons. The association provides education and practice management services for surgeons and allied health professionals.

Mr. Chairman, it is truly a pleasure and honor to introduce Dr. Routman to present before the Committee today.

Chairman SHULER. Thank you, Dr. Routman, for being here today. You have five minutes for your opening testimony.

STATEMENT OF ALAN ROUTMAN

Dr. ROUTMAN. Thank you, Chairman Shuler, Mr. Luetkemeyer, Representative Klein,—thank you very much for that introduction—and members of the Subcommittee.

As Representative Klein mentioned, I am a practicing orthopaedic surgeon in Fort Lauderdale. I represent the American Association of Orthopaedic Surgeons, which represents 17,000 board-certified surgeons across the country.

I appreciate the opportunity to present our concerns today with the many changes being implemented by law and regulation concerning DMEPOS. We share Congress' aims of increasing the quality of patient care, eliminating fraud and abuse in the federal healthcare programs, and reducing the costs of delivering care to our beneficiaries: our patients. It is our pleasure to appear here today to continue our work toward those goals.

With that said, I would like to highlight what we believe to be unintended consequences of applying rules meant for retail DMEPOS suppliers to physicians in small practices across the country who provide certain DMEPOS as part of providing our high-quality care to our patients. This includes orthopaedic surgeons, who treat fractures and apply braces and splits to patients' arms and legs and take care of patients with ambulatory problems, requiring crutches and canes and walkers.

It is important to note that we are talking about doctors who supply these materials to our own patients, not to the public. Because we provide these materials as small businesses and sometimes in rural areas, we are the only suppliers of these materials that we stock in our offices for the care of our patients.

Our concerns that we have regarding some of these new and revised rules pertain not specifically to the competitive bidding process, which I know we are here to talk about today, but I would like to address primarily the accreditation issues as it applies to doctors because we have been lumped in with these businesses requiring this accreditation process.

CMS has signaled, even today, that it might implement what we feel are unnecessary requirements that physicians be accredited like these other businesses to provide DMEPOS to our patients. This threatens to interfere with our continuity of care and our patient relationship.

I would tell you that the rules were changed in May of 2008. I would like to thank Committee Chair Velázquez and Chair Shuler for helping to change those rules. That released the doctors from the competitive bidding process and the accreditation requirements temporarily, but we're looking for a more permanent fix because we are getting signals from CMS that accreditation is down the road for physicians.

We believe that the Secretary of HHS should exercise the authority granted in MIPPA to permanently exempt physicians and licensed healthcare professional from the quality standards and accreditation requirements, considering the licensing, training, and accreditation requirements that we already go through in our states and our societies to practice our craft.

We acknowledge and share your interest in ensuring Medicare beneficiaries receive high quality supplies and quality service. We are equally committed to ensuring that patients have access to the care and supplies they need in a safe, efficient, and timely manner. We believe as orthopaedic surgeons, this can best be provided by us at the point of service.

When I treat a patient with an ankle fracture and they're in my office, I need to make sure that fracture is stable. I can put them in a cast or a brace. But to enable them to get home and to become ambulatory, I need to be able to give them crutches or walkers or canes at that point of service. I can't discharge those patients from my office with an unstable fracture, write a prescription, and say, "Go get this somewhere in the community."

I stock these materials in my office. I submit my invoice to Medicare for my reimbursement. And I am paid a small pittance, perhaps ten percent over my invoice cost. I simply want to provide this to my patients as a service, not for profit.

In order to go through the accreditation process, this would cost doctors $3,000 every 2 years. My total billing for durable medical equipment in the last year was less than that. So to submit me to a $3,000 accreditation process would totally take this out of my office and not allow me to provide this service to my patient.

In addition, I would like to tell you my personal experience. CMS has withdrawn my supplier number. They have made me jump through many hurdles over the last year. I have been providing these materials to my patients over the past year of my own personal cost because of bureaucratic hurdles, the fact that the accreditation process was originally required and then changed.

And I believe that doctors like me are subject to a very large net thrown over the South Florida area, in particular, looking for fraud

and abuse. And we have been caught in that net and been subjected to unfair and inappropriate scrutiny when what we are doing, really, is providing what we feel is quality and medically appropriate care to our patients.

I would like to thank you, Chairman Shuler and Mr. Luetkemeyer, for allowing me to be here today and tell my story. Please allow me and my colleagues to continue to provide high-quality health service to our patients and facilitate their recovery and their ability to health from their musculoskeletal injuries.

[The statement of Dr. Routman is included in the appendix in page 112.]

Chairman SHULER. Thank you, Dr. Routman, great testimony.

Mr. Stanfield is our next witness. Wayne Stanfield is the President and CEO of the National Association of Independent Medical Equipment Suppliers.

Mr. Stanfield, you will have five minutes to give your testimony.

STATEMENT OF WAYNE STANFIELD

Mr. STANFIELD. Thank you, Chairman Shuler and Ranking Member Luetkemeyer, members of the Committee.

As said, my name is Wayne Stanfield, and I am President and CEO of the National Association of Independent Medical Equipment Suppliers, or NAIMES.

Working in medical equipment is a second career for me. I am retired Air Force and spent 20 years in the air traffic control business.

NAIMES is a trade association representing and supporting independent DME suppliers. I also am a partner in an independent DME supply company, Carolina Med-Plus, in the Concord area in round one Charlotte CBA. We participated in the bid but did not win a contract because we bid above the pivotal bid.

NAIMES commends this Subcommittee for examining the impact of CMS' competitive bidding program for DME on small suppliers, which will be profound.

Competitive bidding for DME was a part of the MMA '03. And while the stated purpose was to save Medicare money, that contention gave no consideration to the service to patients and the impact on small businesses, communities, and employment.

CMS contends that DME competitive bidding represents market-based efficiency. I respectfully submit that this program does not represent anything close to healthy market economics. I also note that CMS has ample authority to lower fees without applying competitive bidding.

Competitive bidding makes perfect sense for a multimillion-dollar aerial tanker to replace the aging KC-135, but it makes no sense for an $89 walker or for oxygen services to a senior citizen. Competitive bidding has no place in healthcare and will result in higher costs to Medicare, lower quality, and less access to needed services.

Competitive bidding in itself is an exclusionary process. It is important to understand the gravity of this assault on small business. Since the vast majority of HME providers are small, independently owned businesses, it stands to reason that they will bear the brunt of the effects of competitive bidding.

According to CMS figures in 2007, there were 110,272 supplier numbers billing Medicare. And of those, 103,227 bill Medicare less than $300,000 per year. That is 94 percent of the total supplier community.

It also is important to note that, despite new start-up businesses in the DME industry, there was a decrease of more than 4,000 suppliers from 2006 to 2007. Also notable is that the canceled first round winning bids in the 10 MSAs represented less than 10 percent of the total active suppliers, meaning 90 percent were excluded from the market.

These small businesses are a major part of the engine of the American free enterprise system. They employ more than one and a half million people while serving over 50 million Medicare, Medicaid, and private insurance beneficiaries. These businesses help keep patients out of institutional settings and at home, where they prefer to be, but it is also the least expensive alternative.

The DME segment of Medicare is historically less than two percent of the total Medicare budget. And, in spite of the growth in the Medicare population, this has been virtually flat in growth in expenditures for decades. Yet, this smallest segment of Medicare expenditures is repeatedly singled out for fee cuts, competitive bidding, and other measures, such as the surety bond, all of which are forcing businesses to close and to stop serving Medicare patients.

Homecare and DME should be growing since the cost of this care is infinitely less expensive than a hospital or nursing home. According to a recent market survey by the Freedonia Group, the need for medical equipment will grow by 5.5 percent through 2012, primarily due to the increasing number of older Americans. A program that reduces suppliers at a time when demand is increasing simply defies logic.

This government-sponsored program will eliminate competition by dismantling a national network of suppliers that have reliably serviced the home health needs of Medicare patients for decades. While CMS has developed this program and has released the final rules for its implementation, it is Congress that authorized CMS to pursue this unworkable program.

It is inconceivable that our government would promote a scheme to concentrate market share and eliminate competition at such a crucial time in our economy as we are at this present time. This is a formula for higher prices over time and is bad public policy that must be ended.

NAIMES strongly opposes the reimplementation of this flawed program and recommends that Congress repeal the applicable portions of the MMA '03. Much of the anticipated savings have already been realized through previous cuts, such as the FEHBP cuts in 2007, the elimination of the CPI for the DME industry for more than 5 years, and the devastating 9 and a half percent cut to fees that went into effect on January 1st.

I urge this Subcommittee to support the repeal of competitive bidding and return the free enterprise system to the small independently owned DME providers and allow them to meet the needs of America's aging population.

Thank you, Chairman Shuler.

[The statement of Mr. Stanfield is included in the appendix in page 77.]

Chairman SHULER. Thank you, sir.

Our next witness is Bill Griffin. Mr. Griffin is the founder and President and CEO of Griffin Home Health Care. He his testifying on behalf of the North Carolina Association for Medical Equipment Services.

Mr. Griffin, you are recognized for five minutes.

Mr. GRIFFIN. Thank you, Mr. Chairman.

STATEMENT OF WILLIAM GRIFFIN

Mr. GRIFFIN. It is an honor to be here. And, distinguished members of the Subcommittee, thank you very much.

With my background in funeral service and retail pharmacy, I certainly have a very strong compassion for my fellow man, which is the very reason that I got into this business 26 years ago. I have a passion for the industry and for the clients.

The DME providers of North Carolina were the first in the nation to push for licensure in our industry. CMS reports now that there are 38 states requiring oxygen providers to be licensed.

The DME industry provides a vital part of care for the individuals in our healthcare system. It is very important to understand that the DME Medicare benefits are less than two percent of the total Medicare budget. Obviously much of this a result of small business.

There is no debate that our healthcare system is broken and needs major overhaul. Competition in its purest is very, very healthy. Competition keeps businesses honest, service-oriented, and ultimately keeps prices competitive. My impression is that CMS wants to eliminate competition by eliminating DME providers.

My company was in the first round of the competitive bidding process. The process in itself was antiquated and very cumbersome, to say the least. We bid for five out of the ten product categories. Fortunately or unfortunately, we did not win a single product category.

The information I received from the bid contractor was that our bid prices were too high. Why? Because I looked at my overhead. I schooled myself very carefully before committing to prices that would create substandard service, poor quality products, and ultimately drive us out of business.

There are many troubling issues surrounding the fact that as a stellar organization with a local presence for over 25 years, serving patients, we would now be unable to continue to serve those patients.

The fact that we were told that our prices were too high is a clear indication that many suppliers bid to win, rather than bid to fulfill the commitment of the bid contract.

The DME industry is a Service Industry. It is not a commodity. It is virtually impossible to place a price or a bid on the value-added services for providing and delivering a hospital bed, setting up oxygen or a sleep apnea machine.

I would like to share a couple of the troubling issues. Many of the bid winners had no physical presence in the local communities in Charlotte. CMS awarded these bids to providers that were not

even licensed in the State of North Carolina. Inexperienced and undercapitalized companies were awarded winning bids.

Several of the winners are less than two to four years old. They had never done business in the product categories they had won, nor were they licensed and accredited in these winning categories.

Many businesses will close their doors. One industry expert calculated that only nine percent are going to win the bid. We have heard that already. 91 percent of the businesses will go out of business. Obviously this will do away with thousands of jobs in our country.

In Charlotte, one product category that equals up to 1,200 jobs, you can multiply that times 10 product categories and 10 MSAs just in the first round alone.

To narrow down the results of the competitive bid program for my company, we have eliminated 30 percent of our staffing. That is painful as a business owner.

Full-service DME suppliers can traditionally provide all the DME needs of the patient. Items such as wheelchairs, hospital beds, oxygen, enteral nutrients, and walkers may be provided by as many as five different suppliers under this plan.

How confusing will this be Medicare beneficiaries, caregivers, and those who facilitate the discharge planning for patients leaving the hospital? Access will certainly be an issue.

Case managers have told us they know they can depend on our business because of our service component. Under the Medicare competitive bidding program proposed scheme, the small number of providers will provide substandard service because they will be spread so thin. Patients will suffer. And ultimately there will be a cost shift from paying DME providers to paying for extended hospital stays. Home DME saves the government money.

The reality is that my company lost the bid, but truly I have to believe that we were the winner. I am totally convinced that the number of bid winners are unable to fulfill the commitment. And I feel very strongly that many of the bid winners will not be able to provide the level of care to the Medicare beneficiary.

The poor service will cost our healthcare system additional dollars. It will create hospital admissions and ultimately cost the Medicare program higher prices due to the lack of competition. The DME industry is highly regulated, nationally and locally. And obviously we have already heard CMS requires the companies be accredited by a certified accrediting agency.

In closing, the competitive bidding process is bad policy. It is bad for consumers. It is bad for suppliers. It provides no significant savings to the government. It is inefficient and will ultimately create higher prices.

We ask that the Medicare competitive bid implementation be eliminated. At the very least, let's work with the industry insiders to seek alternatives to preserve the program's integrity, maintain beneficiary freedom of choice in the selection of their provider, and ultimately maintain a competitive marketplace that will drive value-added services with competitive pricing.

Thank you.

[The statement of Mr. Griffin is included in the appendix in page 83.]

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

Our next witness is Gerald Sloan. Mr. Sloan is founder and CEO of Progressive Medical Equipment in Lenexa, Kansas.

Mr. Sloan, you are recognized for five minutes.

STATEMENT OF GERALD SLOAN

Mr. SLOAN. Thank you, Chairman, thank you, Congressman Luetkemeyer, for the opportunity to come and share my story and our industry's small business concerns.

As stated, my name is Gerald Sloan. I am the founder and owner of Progressive Medical Equipment in Kansas City. My company is defined as a small business by the SBA but barely so as defined by CMS.

We will be celebrating our tenth year of doing business this April. And although we specialize in servicing mobility needs, we are a full-line DME company that provides, among many things, standard items, such as oxygen supplies, hospital beds, and bath accessories. This allows us to be a single point of contact for most of our referral sources.

I come before you today to tell the story of competitive bidding from a small provider point of view. Like many small DMEs, across the United States, we began the competitive bidding process with much trepidation and uncertainty.

Although CMS had promised to install safeguards into the system, such as requiring a target of 30 percent small provider participation to protect us, we realized that this actually meant thousands of us would be excluded from the program. Additionally, because the program had no transparency in determining winning bids, we felt and many actually realized that they could be excluded from the program without any refutable cause.

We eventually were selected to participate in four of the five categories that we bid: complex rehab, consumer power wheelchairs, walkers and related accessories, and hospital beds. Although we won our bids, I still feel strongly that CMS did not do enough to protect small providers and ultimately favored large national companies. Evidence of this can found directly from the booklet received by Medicare beneficiaries prior to July 1, 2008 announcing the program and winning providers.

My company, Progressive Medical Equipment, was one of the two local providers to win in the complex rehab category. The other two winners, Scooter Store and ATG Designing Mobility, had never participated in this category in our MSA. To the best of my knowledge, neither is currently doing so.

Also, one would find that the Scooter Store, a national provider for consumer power wheelchairs, is listed three times as a provider to call in our MSA. Everyone else is listed only once.

As for the hospital beds and related supplies category, which features 49 listings, Apria, a national company, is listed 14 times; Lincare, another national company, 14 times; and the Scooter Store 3, times. In other words, 31 of 49 listings, or 63 percent of the listings, were divided among these 3 national providers. No small provider was given more than one reference in this category.

I would also like to point out that the Scooter Store won in every category in our MSA. CMS has been adamant about the quality of

service not being compromised in this acquisition program. But one must ask, how did a company that has never provided oxygen supplies, hospitals, et cetera, let alone be in our MSA, be selected to do so?

Perhaps the greatest and longest-term ramification of the competitive acquisition program for my company rests in our oxygen services. As you may be aware, Congress passed a 36-month cap payment for oxygen concentrator reimbursement. The first of the capped rentals was scheduled to occur in January of 2009.

When we were submitting bids for oxygen, we were still waiting on a final rule of what would happen after the 36-month cap. Questions such as "Who would own the equipment?" and "What kind of service calls would be reimbursed?" were left unanswered by CMS.

Without this knowledge, I felt that as a small provider with very limited numbers of oxygen referrals a month, it would be unwise for me to gamble that the terms of the cap would be financially feasible for us. Therefore, our bid was higher than the accepted bid amount, and we lost the bid.

In anticipation of losing the oxygen category, we began reducing our marketing in this area right after we submitted our bids. By July 1st, 2008, we were down to one to two referrals a month, down from six to ten referrals a month. Just a few years ago, we averaged 75 to 100 oxygen clients. Our number currently stands at 27, 24 of whom are capped out with no reimbursement for our service.

So in short, our oxygen service is dead because of competitive bidding. Not only do we lose, but so does our community, who depends on us for very personalized and committed service.

Another major concern with the competitive acquisition program was the inability to adjust bids because of economic factors. We made bids in the Summer of 2007, long before the price of gas began its well-known spike.

By the time the program started in July of 2008, the price of gas had doubled. The effect of the rise was not only felt in our fleet but in the price of our products as well.

Every supplier we used began adding fuel surcharges to our shipments. Some started requiring minimum orders before they would ship. This had a devastating effect on our ability to maintain the margins necessary to remain profitable. Thankfully, the program only lasted two weeks, but one has to wonder how long could we have lasted in a three-year contract?

In conclusion, I would like to say that the DME industry has been attacked by CMS and Congress for too long for problems we did not create. Fraud has been the ballyhooed cry to justify this persecution. I am before you today to testify that the guilty party is not our industry but CMS.

CMS is charged with maintaining program integrity. Yet, they continue to allow unscrupulous and nefarious criminals access to medicare provider numbers. They have proven time and again that they are poorly managed and cannot deliver program integrity. Yet we are to believe that they have small business interests in mind, that, despite no transparency in the process, we are to trust them with decisions that affect thousands of companies and tens of thousands of employees.

I come before you to ask the Small Business Committee to find a way to strike down this program before it hurts anyone else. Thank you.

[The statement of Mr. Sloan is included in the appendix in page 108.]

Chairman SHULER. Thank you, Mr. Sloan.

At this time I would like to open it up for questions. Mrs. Blackburn, if a competitive bidding process goes through and a large provider that is from outside the state gets a winning bid and they haven't been actively engaged in, say, oxygen, for an example, that requires, obviously, a lot more technical expertize than maybe some of the other equipment does, what is the process for the learning curve? And to what extent? Obviously give me the Reader's Digest version.

[Laughter.]

Chairman SHULER. And to what extent from the patient side, you know, from the health standpoint and quality of care is a problem if someone who doesn't have the expertise that maybe your company would?

Ms. BLACKBURN. Well, first of all, Mr. Chairman, our company is 70 years old. It is independent. But we only entered oxygen probably about eight years ago.

The learning curve has been seven for us. It is an exceptional amount of information that you must know. You must comprise an exceptional staff that is skilled in order to deliver oxygen.

If you go as far as providing liquid oxygen, that is another step that you add to the process. The loss would certainly be to the patient. If you are being provided any type of medical equipment, let alone oxygen, by someone who doesn't understand the etiology of diagnosis, that doesn't understand what happens if they do not provide service immediately, the patient is going to suffer. And the ultimate result would be a hospitalization or at least a visit to the emergency room, which causes an increase to the CMS budget.

Chairman SHULER. Thank you.

This is for Mr. Griffin and Mr. Stanfield. If the competitive bidding process would continue, what would it actually do to your businesses? Mr. Stanfield?

Mr. STANFIELD. My personal business in the Concord market, we would bid again based on our ability to serve. And we would bid a fair market price. It is unlikely that we would win that bid. We would simply exit those categories and try and survive with the rest of the business.

Chairman SHULER. So you would have layoffs?

Mr. STANFIELD. It is impossible to subcontract. If you look at the contract price, which averaged 26 percent below current fees, what is the contract supplier going to pay me?

It is already 26 percent below previous fees. And the offers that we had were 20 percent below the contract fee. Suppliers simply cannot subcontract under this process. So it would essentially take us out of the Medicare market for the product categories that we did not win a bid.

Chairman SHULER. Mr. Griffin?

Mr. GRIFFIN. Very similar. I concur with Mr. Stanfield. We have already taken a little different approach, trying to work towards

some categories, some product categories, that are not included into the bid.

In other words, we have gotten into the baby apnea monitoring business, a totally different field. We have gotten into diabetic shoes, totally apart from the Medicare competitive bidding process, not one of the product categories. A good portion of our business is retail.

Once again, we have laid off 30 percent of our staff. We have exited that number of our staff, just pure and simply, because of that decline in business that we are foreseeing. We will bid again.

Chairman SHULER. Mr. Brant, how about you?

Mr. BRANT. Unfortunately, we would probably be forced to close because it affects 91 percent of the items that we do. Even though they stated earlier that some items would be grandfathered in, enteral feeding supplies, diabetic supplies would not be grandfathered in. And most of our patients would cap within a few months the majority of the business that we put out. So we could not rely on that.

And when you don't win the bid, you can't pick up new equipment. You can't pick up new patients. So, really, we would just be forced to close.

Chairman SHULER. And Mr. Sloan.

Mr. BRANT. Eighty percent of our business is Medicare.

Chairman SHULER. Mr. Sloan?

Mr. SLOAN. I think it is a bit of a difficult question. Naturally, as a small business owner, my first concerns would be taking care of those who have committed to me to work for me. So I would say I wouldn't want to say flippantly that I would just close the door.

I think the net result that we were to lose in certain categories would severely impact our business. And as a business owner, I would have to find other ways of adjusting for that revenue lost.

Would that result in us closing? It is very possible.

Chairman SHULER. Dr. Routman, obviously in your testimony, you said you just started paying it out of your own pocket. I mean, that's quite alarming, but that says a lot about you as a person, that you go far and beyond the call of just being a doctor to the quality of care of the patient. So I commend you for that.

Dr. ROUTMAN. Well, thank you, sir. I still have hope that I will get my DMEPOS supplier number. I have been told that they have 40 or 50 more days to answer my last application. I have probably applied six times in the last year.

But if I don't get the supplier number, I will have to stop providing that service to Medicare patients. And then patients who need those devices will be on their own once they leave my office to try to find those devices, either in the marketplace or struggle to find them somehow.

And my concern is they will find the wrong equipment or they won't be able to find what they need. There will be delays that might cause delays in their healing or untoward complications.

Chairman SHULER. Not to get off on a completely different subject, but the cap, how much did it play in your bidding process?

Mr. BRANT. Which cap, the oxygen cap?

Chairman SHULER. Yes, the oxygen cap. What role did it play in your bidding process? I mean, did you take that into consideration?

Mr. STANFIELD. We did. We took it into consideration considering that we knew that January 1st, there was going to be a change in reimbursement. It did not make sense to bid at a lower rate knowing that we were already going to take a significant cut on the 1st of January.

If I might add, there is another piece of this. One of the things that occurred in our market was Mr. Wilson talked about assuring the service continued for oxygen patients. And it was perhaps more important than a hospital bed.

Yet, there were cases where hospital beds, in fact, kept people in the hospital for extra days at a very high cost to Medicare because under the bid, there was no one available that could deliver a hospital bed within a short period of time to facilitate a discharge.

Mr. BRANT. If I may, one of the things in the Polk County demonstration project is that it was before the legislation of the cap. So people bid in Polk County knowing that oxygen would continue to be paid. But here it began. We knew that we would be capped out six months after the program started. So it definitely had an effect on how we bid.

Chairman SHULER. Well, thank you.

At this time I would like to yield to the Ranking Member for his questions.

Mr. LUETKEMEYER. Thank you, Mr. Chairman.

Mrs. Blackburn, you made a comment during your testimony, something to the effect that CMS disbanded the Oversight Committee. Can you elaborate on it just a little bit?

Ms. BLACKBURN. Yes. The PAOC, or the Oversight Committee, the Program Advisory and Oversight Committee, was directly put together, CMS was mandated to put this committee together, so they could have direct input from the industry leaders and other stakeholders.

They had very few meetings and, in anticipation to this change, just totally ignored the fact that there was a committee there that could feed information to them and possibly educate them on how some of these aspects that would be detrimental to the patients as well as to providers.

And I might add that they just announced their new committee just recently, within the last month.

Mr. LUETKEMEYER. Okay. Also, during your testimony and because you represent an association, I am curious. Have you done any research with regards to the effect on the quality of care as a result of the lack or the bidding process that is in place right now? Has it caused a deterioration of the quality of care of the people? Have you done an assessment of that?

Ms. BLACKBURN. I personally have not done one. And I don't know that we have an assessment on paper that we can give you, but we can tell you that we have dedicated information, the two weeks that we had competitive bidding in play.

And within those two weeks, we had numerous examples of patients having to go to the hospital because the contracted provider could not deliver their oxygen within the two to four hours that usually our referral sources are accustomed to receiving. They were told that they would be there within 12 to 24 hours and in some cases 48 hours.

Now, oxygen is a life-sustaining drug. So we found that totally unacceptable. That is just one instance.

Mr. LUETKEMEYER. During your testimony also, in your written testimony, you have here that the current bid program as it is constituted would eliminate 90 percent of your home providers in the marketplace. Is that your correct assessment?

Ms. BLACKBURN. Ninety percent, yes, of providers. I used the illustration of the fact that CMS has put on paper that they anticipate contracting with less than 400 providers if this new process goes through. And in those nine MSAs, where they would contract with 400 providers, we have 4,127. The math is very simple to do.

Mr. LUETKEMEYER. With this constriction of the number of suppliers, have you done any research to see what kind of increased cost down the road this would be for Medicare?

Ms. BLACKBURN. I don't think I can answer that right off the top of my head. I would say this, that we did take—one of the other gentlemen did mention that we took a 9.5 percent cut when the delay went through with MIPPA.

It is my understanding, although I am not an expert, that the goal was to save one billion dollars a year. The 9.5 percent cut is estimated to save one billion dollars. So, in effect, we possibly have paid for the substitution of competitive bidding already by accepting that cut.

Mr. LUETKEMEYER. Okay. Well, my question is, though, because of the lack of competition down the road, have you done any sort of analysis to see what because of the lack of competition that is going to do to pricing?

Ms. BLACKBURN. Oh, we think definitely pricing will go up. It stands to reason. It stands to reason that the competitive bidding process, which will occur every three years, you must work on the given allowable at that point.

So each time that a provider would bid on a product and they eliminate competition, they have the ability to garner the market. We feel that the cost to CMS will go up because that will be relegated to fewer providers bidding if there's proof on—I am sorry. I don't have that.

Mr. LUETKEMEYER. But you haven't done any survey or research to quantify that? In other words, saying that within two years because the number of competitors is going to decrease, suddenly now you can probably anticipate a 10, 20, 30 percent increase in the cost of doing business because there are fewer competitors in the marketplace?

Ms. BLACKBURN. I am from the Pittsburgh MSA. And my state associate executor director just reminded me of something that was very important. Robert Morris University is in Pittsburgh.

Mr. LUETKEMEYER. Okay.

Ms. BLACKBURN. Our state association got a free market analysis, and the Robert Morris' study determined that this was going to create oligopolies all across the nation, that there would absolutely be increased costs.

And we can provide you, sir, with that study.

Mr. LUETKEMEYER. Yes. I am sure the Chairman and I would love to see some sort of documentation that shows what kind of increased cost we can anticipate because, you know, while the pro-

gram is well-intentioned to try and decease costs, if it does just the opposite, that is exactly what we are looking for, is where this is going to lead to.

Ms. BLACKBURN. We can absolutely get that to you. Congressman Altmire already has that.

Mr. LUETKEMEYER. I appreciate that. Thank you very much.

Ms. BLACKBURN. Sure.

Mr. LUETKEMEYER. Mr. Brant, you had something with regards to—you talked about bonding folks who did bids. Can you explain that to me?

Mr. BRANT. Yes. Actually, I was saying there is no bond. You could place a bid—

Mr. LUETKEMEYER. Right.

Mr. BRANT. —without any financial accountability.

Mr. LUETKEMEYER. Is it normal in your business to place a bond on a bid?

Mr. BRANT. No. We have never had this before, you know, even in the demonstration project.

Mr. LUETKEMEYER. It is required in this? Are you required to do it now, then?

Mr. BRANT. There is no bond. Well, just to bond your company will start in the Fall of 2009, $50,000 bond. But this competitive bidding project, even in the demonstration areas, you could just bid without a bond. And, actually, after you submit your price and you are awarded, if it doesn't work out, you could just walk away. But the artificially low bid you created is stuck there for everyone else.

There has never even a bond. You didn't have to post a bond for your bid, and you still don't have to—

Mr. LUETKEMEYER. Have you looked in the bonding process, whether it is going to cost you extra to be able to be bonded to participate down the road?

Mr. BRANT. Well, again, for the bonding for the company at the end of the year is the $50,000. No, I can't answer that at this time. I think we're still waiting for final rules on that bond that is required.

Mr. LUETKEMEYER. That, of course, would increase your bid.

Mr. BRANT. Yes. But, again, the competitive bidding it won't. But yes, for sure, it would add additional cost—

Mr. LUETKEMEYER. Well, even with the—

Mr. BRANT. —to operate.

Mr. LUETKEMEYER. —competitive bidding, it is going to increase your bid because you have got to include that somehow unless you're just really nice about it and are going to throw it in there.

Mr. BRANT. Yes. Again, what I am trying to say is I don't think it is understood compared to other competitive bid programs in government. For building a building or, as Mr. Stanfield say, building an airplane, those companies have to be bonded. There was never a statement that your bid had to be bonded. Your bid still does not have to be bonded.

Mr. LUETKEMEYER. What is the average bid that you or one of your folks would have to a supplier or to a purchaser? What would the average—you know, what would you throw out for your local—whoever you are going to sell something to tomorrow? What would your average bid be?

Mr. BRANT. That is hard to say.

Mr. LUETKEMEYER. A thousand?

Mr. BRANT. It depends on which item.

Mr. LUETKEMEYER. Ten thousand? A hundred thousand.

Mr. BRANT. Well, I mean, on each individual item, I mean, there were hundreds of items that we bid on different categories. But considering my company only made a three percent profit over average the last few years, we couldn't really come up with a price that was more—we pretty much knew when we put in our bid what would be just a few dollars below what the current Medicare reimbursement was because we couldn't live with it.

Mr. LUETKEMEYER. Well, what I am getting at, if you are going to be bonded, I am trying to figure out what the size of a normal contract would be.

So, in other words, if you have a $30 million business and you have 1,000 customers, that would be a certain amount of money per bid, trying to get to an idea to see if this bonding is even worthwhile. That is where I am going with it.

Mr. Stanfield, can you answer that?

Mr. STANFIELD. The bonding from my perspective as a representative of the independent suppliers is not a sensible process. It is simply going to eliminate another whole core of small businesses that cannot afford. As in the case of the physician here to have a surety bond would make it impossible for a company that only does a few thousand dollars a year to be able to afford that because the bond would exceed the return, much as accreditation would exceed it.

We feel that the surety bond requirement has been far outweighed by the accreditation requirement, which is now mandatory and everybody agreed that that is an important part of reducing fraud and abuse.

Mr. BRANT. I would say that with the amount of equipment that we would put out in an annual year with Medicare would be like $800,000. So to have a bond to be $800,000, I have checked. I think it was somewhere about $10,000 a year additional operating cost for that type of bond.

Mr. LUETKEMEYER. Normally I would think that a bond would be more beneficial in the area of services versus area of product. To me, if you're going to give 100,000 of the product, you're either going to deliver it or you're not. A hundred thousand worth of services is a different situation. That is a situation where you may need to be bonded.

But, I mean, Mr. Stanfield, with your association, what is the average sale of merchandise to an entity?

Mr. STANFIELD. Well, it is an interesting anomaly because of the figures I gave you. I think it was about 103,000 of the total supplier numbers out there billed Medicare less than 300,000 a year.

When you look at those raw numbers, many of those provide even smaller, more than 50 percent of those, supply Medicare probably less than 15 or 20,000 a year because they are pharmacy-based suppliers.

Mr. LUETKEMEYER. So, basically, what you are saying is the accreditation of the individual or the company that is providing the

services, then, or selling this equipment is much more important versus the bond?

Mr. STANFIELD. Absolutely, much more.

Ms. BLACKBURN. Absolutely.

Mr. LUETKEMEYER. We got a lot of nods on that one.

Mr. STANFIELD. It just took a while to get there.

[Laughter.]

Mr. LUETKEMEYER. Oh, well. This is Washington. It takes a long time to get anywhere around here.

Mr. Stanfield, also I asked the same question of Ms. Blackburn a minute ago. Do you have any information with regards to the overall increase that you would see in the cost of delivering your goods and services if you—

Mr. STANFIELD. Again, it is very clear.

Mr. LUETKEMEYER. It is in there? Okay.

Mr. STANFIELD. It is very clear from the Robert Morris University study. Dr. O'Roark and Dr. Foreman prepared this [This study is included in appendix in page 123].

Mr. LUETKEMEYER. Okay.

Mr. STANFIELD. And I do have a copy here that you are welcome to take today if you would like.

Mr. LUETKEMEYER. Are you willing to put that into the record as part of your statement?

Mr. STANFIELD. I believe it already is. John, is that not a part of the record from last year?

Mr. LUETKEMEYER. I think this is a—

Mr. STANFIELD. It was last year, but we can submit it again.

Mr. GRIFFIN. From May, I believe it was, Mr. Chairman.

Mr. LUETKEMEYER. Thank you. I appreciate that.

Mr. GRIFFIN. And also there is another study, an independent study, by Dr. Katzman that you have from the May hearing.

Mr. LUETKEMEYER. Okay. Mr. Griffin, during the course of your comments, something came up to me. If we had scheduled rates, is there anything that could be done if somebody wanted to negotiate a different rate?

In other words, if you are going to sell a piece of equipment or you are going to sell the services and it's going to be scheduled by CMS versus a bid, if it went to a schedule, for instance, I mean, hypothetically here? Is there anything? Could you not negotiate with someone a different rate on that or is that once the schedule is set, it is set?

Mr. GRIFFIN. Let me answer your question and then probably ask you a question, please, sir. Some years ago when I was president of our state association, I worked with the State of North Carolina and our Department of Facility Services, DFS, with Health and Human Services. We actually went down the fee schedule for Medicaid because the management of Medicare, of North Carolina Medicare, wanted to move towards competitive bidding.

The DME providers, including myself, and people with Health and Human Services got together. And we went through the entire Medicare fee schedule item by item by item. There was give, and there was take from industry and from Medicare on each individual item to decide what was appropriate. Medicare knew what

we were paying for items. They also looked at and respected the cost that we had for delivering certain items.

At that time, when we went through that Medicare fee schedule in the State of North Carolina, they came back to us to say that there would be a $10 million savings just on that one exercise.

I have talked to a member of the PAOC a few minutes ago. And we could very easily do that with Medicare. We could sit down with industry insiders. We could sit down with CMS. We could review the entire fee schedule. We would have to do it in product categories.

It would have to be very methodical, very analytical. We can do this. And there would be some give and take.

Mr. LUETKEMEYER. Would you suggest this be done on a state-by-state basis or at the federal level?

Mr. GRIFFIN. Possibly regional. We have got the four MACs. We have got the four CMS MACs.

Mr. LUETKEMEYER. Okay.

Mr. GRIFFIN. It could potentially be done regional.

Mr. LUETKEMEYER. Okay. Very good.

Mr. Sloan, you made a comment or I think somewhere I was reading here that 80 percent of the suppliers are small business folks. Is that pretty much correct?

Mr. SLOAN. That wasn't my comment, but I—

Mr. LUETKEMEYER. I think it is—

Mr. SLOAN. Was it about 90 percent?

Mr. LUETKEMEYER. Ninety percent?

Mr. SLOAN. Ninety percent.

Mr. GRIFFIN. I think it is in excess of 90 percent.

Mr. LUETKEMEYER. Okay. And this, the competitive bidding portion of this, says we only have to have a minimum of 30 percent be small business owners. In other words, we are protecting 10 percent and exposing, getting rid of 60 percent of the people, just at least not allowing 60 percent of the small business people to bid here. Is that where we're headed with this?

Mr. SLOAN. I believe that they say a minimum of 30 percent. I don't think it has to be 30 percent, then they cut off the small providers. But yes, 30 percent is the maximum.

Mr. LUETKEMEYER. What I am trying to get to, though, is, in other words, if we would have something in there that says 90 percent, that 90 percent of the group or 80 percent or 75 percent of the group needs to be small business owners versus there is only 10 percent are large producers or large suppliers. I mean, we have got this kind of balance, do we not?

Mr. SLOAN. I believe so, yes.

Mr. LUETKEMEYER. I am just curious. You are part of the research here, I assume, the study that will show us what kind of impact it would have?

Mr. SLOAN. I am familiar with it, although I was not involved with it.

Mr. LUETKEMEYER. Right. Okay. Very good. And you made a comment about provider numbers need be more, that CMS need be more scrupulous on how they provide provider numbers so there is less fraud. Is that a problem right now for me to be concerned about I need to look into?

Mr. SLOAN. I believe it is an ongoing problem.

Mr. LUETKEMEYER. They are not screening these correctly or are allowing them—they are not accrediting the people correctly or—

Mr. SLOAN. I believe we are not making site visits. CMS is required to make sure there is an operation in business that is applying for a Medicare provider number. These are not just taking place currently.

I heard stories that through competitive bidding, it did not take place. So how can we trust them to maintain the integrity of the program, any program, for that matter if we're not investigating the people who are applying for the provider numbers?

Mr. LUETKEMEYER. Right.

Mr. SLOAN. Accreditation, which is part of the solution, I believe, is the first part of that.

Mr. GRIFFIN. Mr. Luetkemeyer, I think Ms. Blackburn can tell you that our national association has put together a list, I believe, of 13—

Ms. BLACKBURN. Yes.

Mr. GRIFFIN. —different qualities aside from licensure, aside from accreditation that would insist that the provider and that CMS do certain things to continue to work with and provide Medicare services.

Mr. LUETKEMEYER. Fantastic.

Mr. STANFIELD. Mr. Luetkemeyer?

Mr. LUETKEMEYER. Yes?

Mr. STANFIELD. If I might make a comment as well regarding the site inspections? It is an interesting process. CMS contracts with the National Supplier Clearinghouse, which is an independent company. They subcontract with another company to oversee certain aspects of compliance. And they subcontract with someone else, who subcontracts with individual people to do the inspection on the sites.

The site inspector that came to my company was a boiler inspector. He had never been to a DME company in his life.

Mr. LUETKEMEYER. Was a what kind of an inspector?

Mr. STANFIELD. He was a boiler inspector. We have had elevator inspectors, boiler inspectors, building site safety inspectors, auditors of this type that come to our companies—

Mr. LUETKEMEYER. He is an expert in medical equipment?

Mr. STANFIELD. He came into the building and said, "I see medical equipment" and checked that off. And that was sort of the process that went through. That has been repeated numerous times across the country.

Mr. LUETKEMEYER. Thank you.

Ms. BLACKBURN. Mr. Luetkemeyer?

Mr. LUETKEMEYER. Yes?

Ms. BLACKBURN. If I could add one thing, it is that the NSC, who is contracted by CMS, the National Supplier Clearinghouse, is the entity that has the charge to make sure that any provider number that is given to a provider is legitimate.

There is inventory. There is a store there. There is the ability to service a client. And not to what you read, we all read, in the newspapers, the national newspapers, the Wall Street, the New York Times. If you do your homework and you go back, you see that

company should not have had a number in the beginning. It was not a company. It was a front.

And so we consistently go back to, how did they get the provider number? This is hurting our industry. And we have to make CMS accountable for the oversight that they are to be giving this contract.

Mr. LUETKEMEYER. I am finished. I want to thank each of you personally for coming today. And I want to work with the Chairman here. We have some ideas on things that we want to do and certainly look forward to working with each of you. Again, I would be more than willing to have you contact my office to be able to give us further information or any kinds of questions you may have about it.

Mr. Chairman, with that, I will yield back.

Chairman SHULER. Yes, sir. Thank you.

At this time I would like to yield five minutes to the gentleman from Pennsylvania, Mr. Thompson.

Mr. THOMPSON. Thank you, Mr. Chairman. I want to thank the Chairman and Ranking Member for going down this road. To me this is an important area.

I am a fresh face around here, just six weeks. And I come from, a nonprofit community health care background, working with a lot of older adults, rehabilitation, and as a licensed nursing home administrator. So this is an extremely important issue. I have a couple of obvious concerns I am looking forward to expressing today.

Thank you to the panel, too, for your testimony and all of your information. It is very much appreciated.

My concerns looking at this whole topic really have to do with two things, probably a lot of things but primarily cost, what it does to cost, and what it does to complexity, cost in terms of ultimately concern with what this will do as we reduce competition over time and drive cost up in terms of access and affordability and complexity in terms of the consumer is older adults. And these are folks who, with medical complexities will have a real hard time dealing with distant suppliers, multiple suppliers, and ownership over equipment they need to use but they don't understand how it works; some real issues.

Now, I guess my first question I would like to throw out to the panel, just some general reaction, to see what your reaction is to those folks, like myself, who have this concern that because of what is proposed and what we are looking at can really take some of the most at-risk adults who are aging with dignity in their homes and would actually drive them back into institutional settings because of issues related to cost and the complexity.

Any thoughts in terms of what risk we run in that situation?

Ms. BLACKBURN. I would like to start the conversation, if I may. I think part of the basis of competitive bidding came from the demonstration projects in Polk County and San Antonio.

What is a fallacy is that there was a true savings there because anything that might have caused a patient to go to the emergency room, go to a hospital because he wasn't receiving care would be charged to the Medicare part A budget. And there was absolutely no cross-referencing of spikes in Medicare part A, as opposed to any losses in Medicare part B. So that is the first issue.

I think one thing that we all can say is that when patients don't get care—and many of them depend on our agencies, they don't have family members, they don't have spouses to care for them, they go to the hospital. They go to the emergency room.

And, again, that is a cost to the Medicare budget, but it's in part A. And there has never been an analysis of how that cross-references.

Mr. THOMPSON. All right.

Ms. BLACKBURN. And we would expect that to happen over and over again.

Mr. BRANT. I would say that one problem we had in Miami MSA is patients received these booklets from Medicare. And I actually had a patient that I had for some time that the patient called me up and said, "Well, I don't see you on this list. So I think I need to get my equipment picked up and try to find another supplier" that was listed in their city. And there was no one in their immediate city. And it was very confusing for the patient.

We actually had a company that was a bid winner but they didn't have the d/b/a name of the company listed—was sent out to the patients. And they told them, "Well, I need to change my supplier."

It became very frustrating for the bid winner, who had to try to explain to the patient, and the patient, saying, "Well, I'm sorry. I have got to work with my doctor and try to get one of these other companies to provide me the service that I need."

And that was a real problem, a lot of confusion for the patients. And, actually, it is still going on from the cleanup that happened in July.

Mr. GRIFFIN. Mr. Thompson, last week in Charlotte we had a very small little snow shower, but it resulted in ice. Mr. Shuler can probably tell you that in North Carolina, just a little bit of snow will shut local communities down.

The very fact that we went in the Charlotte CBA from approximately 130 oxygen providers down to 11 oxygen providers under this current competitive bidding scheme should be evidence enough that those 11 providers cannot provide the oxygen support and services. If their power had gone out, if there had been ice on the power lines and their power had gone out, you can't deliver oxygen services in that broad of an area by 11 suppliers.

I was delivering oxygen during Hurricane Hugo. For about 11 days I delivered oxygen tanks. And I know some of my colleagues here have delivered oxygen in Florida and different places. You can't do it with the smaller numbers of suppliers.

So, yes, the Medicare beneficiary is going to the hospital.

Mr. THOMPSON. Thank you.

Mr. SLOAN. If I could add to that, you know, I don't think we can underestimate the value of what the service is provided by the small provider. For many of us in our communities, these are our neighbors, our relatives, our friends. These are not people who are Medicare members or beneficiaries. They are very important to us as people.

I am sure I speak to many people in this room when I say when certain clients come into our office, everybody knows and smiles and says, "It is Mrs. Smith again," but we rush out and we take

care of Mrs. Smith. That is what we do. That is how we have built our business.

Under a program like this, where price becomes the issue and our product is made more to look like a commodity, our service is ignored completely I think is missing the whole point of healthcare, which is what we are: healthcare providers.

Dr. ROUTMAN. I would echo that sentiment, sir. I believe service is what we provide to our patients. As a physician, the outcome of my patient is important to me. I am outcome-driven. I want everyone to get a good result. That makes it important for me to make sure they get the right device, that it fits them properly, that I am sure that is going to take care of their problem.

Medicare doesn't reimburse me for that. That is okay. I want the best outcome for my patient. Medicare is busy crunching numbers and worried about bidding and cost. We are worried about our patients and to service our patients, which they really haven't quantified and haven't addressed.

Mr. THOMPSON. That is certainly an inherent value I have seen in mom and pop providers. They care about the people. They do much that goes above and beyond what they are paid for.

Mr. Chairman, it looks like my time has expired. Thank you.

Chairman SHULER. Thank you, Mr. Thompson.

I want to thank all of the witnesses for their testimony today. And I look forward to working with the members of the Subcommittee and the Small Business Committee as a whole to work through some of these issues in this legislation.

I ask unanimous consent that the record be open for five days for members to submit their statements. Hearing no objection, so ordered.

This hearing is adjourned.

[Whereupon, at 12:06 p.m., the subcommittee was adjourned.]

STATEMENT OF

LAURENCE D. WILSON
DIRECTOR, CHRONIC CARE POLICY GROUP

CENTER FOR MEDICARE MANAGEMENT
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

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

BEFORE THE

HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP

FEBRUARY 11, 2009

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
Subcommittee on Rural and Urban Entrepreneurship
On

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

February 11, 2009

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

Overview

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

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

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

Table 1: Illustrative Comparison Prices Pre-Competitive Bidding

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

[1] Department of Health and Human Services, Budget in Brief: Fiscal Year 2009.
[2] CMS Office of the Actuary, 2009 Mid-session Review.

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

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

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

[3] *See* 72 Fed. Reg. 18079 (April 10, 2007)

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

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

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

Background

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

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

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

[4] CMS data derived from bid results

[5] http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2993&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date

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

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

* Suppliers retain ownership of oxygen equipment after end of rental payment period of 36 months. Suppliers must transfer title of capped rental items (e.g. hospital beds) after the end of the rental payment period of 13 months.
** 20% of current and new allowed amount is paid by the beneficiary out-of-pocket using 2008 allowed amounts

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

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

[6] Average of the single payment amounts for the various competitive bidding areas.

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

Quality and Financial Standards

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

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

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

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

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

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

[7] *See* 74 Fed. Reg. 2873, 2876 (January 16, 2009).

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

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

Implementing Regulations

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

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

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

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

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

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

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

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

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

policies and implementation pay close attention to the concerns of these constituencies, in particular those of small suppliers.

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

- CMS worked in coordination with the Small Business Administration (SBA) to develop an appropriate definition of "small supplier" for this program. Under this definition, a small supplier is a supplier that generates gross revenues of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue rather than the SBA's previous standard of $6.5 million. We believe that this $3.5 million standard is representative of small suppliers that provide DMEPOS to Medicare beneficiaries.

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

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

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

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

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

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

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

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

Outreach

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

Conclusion

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



House Committee on Small Business

Subcommittee on Rural Development,
Entrepreneurship and Trade

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

February 11, 2009

Testimony of Georgetta Blackburn
Vice President, Blackburn's
On Behalf of the American Association for Homecare

Good morning, 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 also vice president of government relations and legislative affairs for Blackburn's—an independently owned home medical equipment company based in the Pittsburgh metropolitan area for over 70 years. 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.

The American Association for Homecare (AAHomecare) 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 home 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.

Overview

The Association welcomes the scrutiny of this Subcommittee hearing to re-examine the Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) bidding program and its impact on patients and providers who furnish high quality homecare equipment and services to millions of Americans.

Since the last hearing before this Subcommittee in June 2008, Congress legislatively delayed the bidding program for a period of 18-24 months and directed the Centers for Medicare & Medicaid Services (CMS) to address the troublesome and problematic results from the first round of bidding.

But instead, CMS made as few changes as was possible under the law in order to issue a rule quickly on the final day of the previous administration with no structural changes to the flawed program. In rolling out the program in this manner, there has been no opportunity for any public comment or evaluation of the problems that plagued round one throughout 2008. Late last year, the Agency also disbanded the advisory body, the Medicare Program Advisory and Oversight Committee (PAOC), which Congress mandated to advise CMS on the program. While the PAOC is now being reconstituted, it has never met to review the problems that hampered the initial roll-out of the program or to consider any public input on changes made by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

The bid program as currently constituted:

- **Eliminates approximately 90 percent of homecare providers in a marketplace;**
- **Lowers quality and access to care for seniors and people with disabilities;**
- **Reduces competition and limits choice by shutting out the majority of qualified providers;**

- **Ignores the fact that the home medical sector is the slowest-growing portion of Medicare;**

- **Fails to understand the reality of how home medical equipment and services are provided.**

We believe that the efforts by CMS to hastily re-implement this program will have deleterious and long-lasting results for all homecare providers and patients. Congress must permanently suspend the Medicare bidding program for home medical equipment and services in order to prevent reduced access to care for beneficiaries and diminished quality of care. Providers of home medical equipment face serious disruption to their businesses if competitive bidding becomes the primary mechanism for Medicare to set reimbursement rates.

Impact on Small Home Medical Equipment Providers

Competition is an American hallmark. Homecare providers currently compete on the basis of quality service, as providers are reimbursed according to Medicare's fee schedule. Yet, this CMS-designed program is anti-competitive and fundamentally flawed. It will eliminate 90 percent of the homecare providers—typically small, family-owned businesses—in any marketplace where it is implemented. Analyses conducted by CMS show that the Agency is anticipating that the upcoming roll-out of the revised bidding program will result in less than 400 companies to provide services in these areas. Currently, 4,127 companies service Medicare beneficiaries in the nine metropolitan statistical areas (MSAs).

In our view, the program will consolidate the market in the hands of a few through a selective and restrictive contracting process. It constitutes a government-mandated consolidation of the marketplace that will lead to significant job losses precisely at a time where the government is making efforts to stimulate job creation.

Further, a program whose primary selection criterion is product price represents a "race to the bottom" that will jeopardize quality and access to care for millions of Medicare beneficiaries. The Association has predicted these outcomes since the program's inception. Several economic studies also have anticipated similar results. These predictions became reality when the program was implemented for two weeks in July 2008, when Congress had to step in and delay the program.

Program Flaws That Precipitated Congressional Delay

The initial roll-out of the bidding program in July 2008 produced troubling results for the home medical patients and for the providers that were unfairly excluded from Medicare as a result of the first round of bidding. As a result, Congress enacted MIPPA, which included a delay and reform of the bidding program in order to improve the process, establish quality measures, and make other needed reforms. During the implementation of Round One, before passage of MIPPA, numerous problems were encountered including:

- **Disruption to patient services** – Patients were forced to go to multiple, unfamiliar providers for different items and services;

- **Greater costs to Medicare due to longer hospital stays** – Due to delayed hospital discharges, unnecessary emergency room visits, patient confusion and disruption.

- **Erroneous disqualifications** – Nearly two-thirds of accredited providers that submitted bids were disqualified based on CMS errors and non-substantive reasons;

- **Non-local providers** – Providers with no history of servicing a geographic region or no business operations in a bidding area were awarded contracts;

- **Inexperienced/unlicensed providers** – Providers were awarded contracts for equipment and services they had never provided before or that they were unlicensed to provide; and

- **Desperation bidding** – Structural flaws in the bidding program caused providers to submit artificially low bids because they were faced with the threat of losing their businesses if not awarded a contract. Winning contracts were viewed by many as commodities that could be sold.

Several of these issues were addressed by MIPPA, such as notification to the provider of missing financial documentation to ensure companies are not inappropriately disqualified, as well as a requirement that any provider must notify CMS of its subcontracting arrangements to provide care to ensure that an entity is appropriately accredited. But most of the problem areas will arise again if the program is re-launched.

The following is a snapshot of the first round of this bidding program gathered from CMS data:

- A total of 2.6 million eligible Medicare beneficiaries will be impacted in the first 9 markets of the bidding program;

- A total of 4,127 homecare companies currently serve the first 9 markets;

- A total of 1,335 contracts from 376 unique homecare companies were awarded in the first phase of the program last year. This means that 3,751 companies did not "win" contracts and thus were barred from providing bidded items and services to Medicare beneficiaries. Since the average home medical equipment company typically does about 40 percent of its business with Medicare, the loss of Medicare as a revenue source will lead to serious financial difficulties and outright closures for the vast majority of these companies because they cannot survive for the three-year contract period;

- The ratio of beneficiaries to providers would have increased by 339 percent in the aggregate across program areas. This will greatly overwhelm the patient referral system, reducing access to care and result in increased hospital stays since "winning" providers may be unable to handle the increased patient load;

- Nearly 1/5th of all beneficiaries on oxygen—223,900 patients—will be impacted in the first phase of the program;

- A total of 143,400 diabetic patients could be forced to switch providers and use lower-quality glucose monitoring devices;

- A total of 214,000 patients on tube feeding could be forced to switch providers, and the winning supplier list is likely to be too small to accommodate a large influx of transitioning patients;

- In an informal test of the program, 133 referrals made to winning suppliers in six of the bidding areas resulted in:

    - Over half of referrals to contracted providers were turned down for various reasons related to their inability to serve the patients;

    - Over 60 percent of referrals for patient services that were made to contracted providers resulted in untimely delivery; suppliers responded that they could not provide same day service (same-day is expected by referral agents); and

    - Over 40 percent of referrals could not be serviced due to contracted providers' inability to service patient's zip codes or not answering the telephone at all.

Beneficiary Access Problems

- In Miami, pulmonologists reported being told that oxygen services could not be delivered for 2-3 days by winning contractors. Prior to July 1, standard delivery timeframe to patients had been 2-4 hours;

- In Riverside, CA, 100 percent of out-of-state contract winners for CPAP/Bi-level sleep therapy equipment had rejected referrals, stating that they "don't service the area" or "that's too far";

- In Kansas City, 27 percent of referrals (i.e. orders) placed for walkers, enteral, oxygen or CPAP equipment and services had resulted in contract providers refusing those referrals because they could not service the area or did not have the equipment.

    - Five of the 11 contract suppliers contacted in the Kansas City CBA had no local office; this was the reason offered in two of the turndowns. The remaining providers stated they could only drop-ship the products and that it could take between several days and two weeks;

    - An out-of-state contract provider from California told Kansas City and Pittsburgh referral sources that they were not sure they could supply a walker to patients in those CBAs, but if so, it would be shipped by UPS and could take 10-12 days to deliver;

- One enteral nutrition contract provider said they only supply nursing homes–not homecare patients;

- One provider for the walker product category said they only service one small town in Kansas and cannot accept referrals across the Kansas City metro area.

- In Charlotte, based on 23 referrals that were transmitted to contract providers for CPAP, enteral, liquid oxygen and oxygen equipment and services, contract providers said "no" 30 percent of the time, and another 30 percent of referral contacts resulted in no answer at the business' phone number. Of the 30 percent of oxygen referrals turned down by winning providers in Charlotte:

    - 57 percent of the refusals were due to an out-of-state, contract supplier not having a state license to provide oxygen in North Carolina;

    - 14 percent were due to the patient being located "too far" away in the CBA;

    - 28 percent were due to the supplier not having the product in-house or having decided not to provide liquid oxygen--despite the Medicare mandate that providers supply all HCPCS products.

- All out-of-state winners for CPAP are determined to drop-ship the devices to patients in North Carolina which is a clear violation of the North Carolina State Respiratory Care Board.

Association Concerns with Interim Final Rule

In June 2008, the House Subcommittee on Health of the Committee on Ways and Means held a hearing examining the competitive bidding program. Testifying before the Subcommittee, CMS Administrator Kerry Weems told the panel that changes to the program were not necessary.

Congress disagreed and passed MIPPA. MIPPA contained provisions that would require CMS to go through the complete rulemaking process to address problems with the bidding program.

An 18 to 24-month delay was required for CMS to publish a proposed rule and ensure that comments received during the comment period would be taken into account. The homecare sector paid for the delay with a significant fee schedule payment cut on all competitively bid items--9.5 percent--which began on January 1 of this year.

However, instead of taking the required time to redraft the rule, CMS moved swiftly to restart the program and issued an interim final rule just six months after MIPPA was enacted. The speed with which this rule has been reissued and lack of public deliberation again raise serious fundamental questions about the program.

The following examples are questions about the process and the willingness of the Agency to engage in public debate:

- **Lack of adequate changes to bidding** – CMS has done the bare minimum to comply with MIPPA, which affects healthcare for millions of beneficiaries. Because Round One of the government-mandated consolidation program was fraught with flaws, the new rule raises serious questions about due process, fair selection of providers, and patient access to care.

- **No input from stakeholder advisory committee** – When Congress enacted the program, it mandated that CMS create a Program Advisory and Oversight Committee (PAOC) composed of homecare stakeholders to provide guidance on implementation of the program. Since MIPPA was passed, CMS disbanded the PAOC and drafted an interim final rule with no PAOC input.

- **No public input** – The effective date of the interim final rule is February 17, 2009—just 30 days after publication, leaving no opportunity for CMS to receive comments from industry stakeholders to incorporate into a final rule before the program is re-launched.

- **Abuse of the system and inappropriate rulemaking process** –The issuance of interim final rules is generally reserved for healthcare *emergencies*. This clearly was neither such a case nor the intent of Congress in enacting the delay.

Additional Association Concerns

CMS has never fully explored fundamental problems that occurred during the first round of the program. We have the following concerns that CMS has never ventured to address:

- There was significant variation in bid rates for the exact same product billing codes across bidding areas. This issue has never been evaluated to determine if the allowables set under the program were appropriate.

- Homecare companies that had no experience providing patients with a product category or were not located in the MSA were offered winning contracts. These issues have never been vetted to determine the effects of this methodology on beneficiaries.

- There was no transparency related to the evaluation of the bidding packages. CMS has never come forth with its methodology to review a complex bidding package. There is no confidence that the staff charged with this critical responsibility have the expertise and experience to evaluate a provider's submitted material that would make it eligible and viable to serve the marketplace.

- CMS has never explored the financial impact the program would have on a company that previously provided the full complement of bidded items to Medicare beneficiaries but "won" only one or two product categories. If a company provided hospital beds, walkers, CPAP and oxygen therapy but only "won" the walker category, we believe that any non-

specified volume increase in walker orders would not be able to make up for lost business in its other core lines of business.

- In a related bidding problem, since the contract offered by CMS to homecare companies has no volume guarantee, it is impossible for a homecare company to submit an accurate bid under the program. The program creates an environment of "irrational bidding" by creating circumstances where providers had the choice of submitting a bid or losing their business. It is our understanding that some providers submitted bids to practice or to "win" a contract and sell that contract to another provider in the marketplace. The contract in this case becomes a commodity to buy and sell through the bidding process.

- CMS touted that the program worked because 63 percent of the "winners" under the program met the definition of a small provider. CMS has never evaluated why large companies who can reasonably be assumed to have economies of scale, stronger purchasing power, and the ability to determine costs more accurately than smaller companies were not the predominant "winners."

- CMS' Interim Final Rule (IFR) to re-implement the program indicates that it will be issuing "sub-regulatory guidance" on a number of facets contained in the IFR. The homecare community has little confidence that CMS will issue these directives in a timely and appropriate way that allows for public input. A key concern arising during the run-up to implementation last year was inaccurate and conflicting guidance provided by the contractor and CMS personnel.

Anti-Fraud and Abuse

During the debate on the program last year, CMS frequently cited that the program was an anti-fraud and abuse mechanism. This characterization is incorrect. It is, rather, simply a payment mechanism. We believe that the reason CMS called the selective and restrictive contracting program a fraud deterrent was to make it more difficult for policymakers to question the underpinnings of program.

The Association has no tolerance for fraud as it wastes scarce Medicare resources. We have, therefore, developed a 13-point anti-fraud and abuse plan aimed at routing out fraud and abuse from the DMEPOS category and look forward to discussing our proposal with this Committee and other policymakers.

However, CMS and its contractors must shoulder the primary responsibility on permitting fraud and abuse to persist. The Agency can most effectively stop fraud in its tracks through better oversight and management of its subcontractor, the National Supplier Clearinghouse (NSC). The NSC is charged with granting Medicare DMEPOS billing privileges to homecare providers. CMS must require the NSC to fulfill its mandate and only grant billing privileges to legitimate homecare providers.

Conclusion

Homecare is the most cost-effective model when compared to any other institutional health care setting. Additionally, homecare companies contribute to local economies. Providers of medical equipment are part of the continuum of care; they deliver, setup, and educate the patient and caregiver, monitor compliant use, and answer emergency calls 24 hours a day.

The latest federal data shows that spending on home medical equipment is again the slowest-growing sector in Medicare, with homecare proving to be one of the smallest sectors, constituting $7 billion out of the $431 billion Medicare budget. Medicare spending for home medical equipment increased only 0.75 percent over the previous year for which data is available (2006), while Medicare spending generally increased by a full 6.1 percent.

The CMS-designed DMEPOS competitive bidding program is anti-competitive. It will result in thousands of small business failures. It will result in thousands of job losses across the country. It will limit access to homecare products and services. It will reduce the quality of care provided to Medicare beneficiaries. And it will likely result in higher costs for the Medicare program as hospitalizations and admissions to long-term care facilities increase.

The Association strongly recommends that Congress act promptly to permanently suspend the bidding program. Until this can occur, we ask that Congress request that the current Administration rescind the rule before it can permanently harm the homecare sector and Medicare beneficiaries we serve.



February 9, 2009

Written Testimony for Hearing:

WEDNESDAY, February 11, 2009, 10:00 AM
"The Impact of Competitive Bidding on Small Businesses in the Durable Medical Equipment Community" - House Committee on Small Business, Subcommittee on Rural Development, Entrepreneurship and Trade

My name is Robert Brant, I am the co-owner and manager of City Medical Services in North Miami Beach, Florida and I am currently the President of the Accredited Medical Equipment Providers of America (AMEPA), an organization formed shortly after the
bid results were announced last March, by bid winners and loser from the Miami, Orlando and Dallas MSAs, all opposed to the Competitive Bidding program.

The goals of the Competitive Bidding program were to reduce the Medicare Reimbursements, reduce Medicare fraud, and to responsibly minimize the number of providers for CMS to manage without limiting patient's access to care.

The fact is, in the last 10 years, with the passage of new rules and regulations, all of the goals that once justified competitive bidding have already been achieved. The industry has negotiated a 9.5% cut to providers and withheld another 5% CPI increase, which both began on January 1st. This is a 14.5% net savings to Medicare. The annual cost to mange the program is set at $22 million, which if terminated, would save an additional 2% or 16.5% overall, nearly the same percentage of savings from the first round of the demonstration project. Also the number of providers has been substantially reduced by firm closings due to the cuts and mandatory inspections which were implemented 2 years ago.

Despite that good news, Medicare released interim final rules on January 16 of this year in order to restart the program, using the same methodologies and techniques to award contracts. CMS plans to reenact the same program, which allows bidders to bid without any financial accountability or regard for state laws, including unlicensed, out of state and out of area bid winners, with no history of providing bid equipment and services throughout the first 10 MSAs. In fact, it was in a similar Small Business Committee Hearing to this, that Congressmen Altmire and Gomert said the program failed to meet Regulatory Flexibility Act requirements, 6 months before bid results were announced.

This program is flawed, but not just the recent program.

This all began in a flawed 3 year demonstration project in Polk County, Florida between 1999 and 2002. From this small project in a mainly rural county, Medicare claimed the program was not harmful to small businesses because no one closed during the demonstration, but that was because the 4 categories chosen over the three years made up only 35% of the products provided, mainly oxygen and hospital beds. Providers survived the demonstration by providing CPAP, Respiratory Assist Devices, Power Wheelchairs, Diabetic Supplies and more. The current program even after the MIPPA changes were enacted would stop those who did not win the bid from providing 91% of the equipment to Medicare beneficiaries, essentially driving them out of business.

Although the first round of the demonstration project had a total savings of 16.7% it is important to realize that most winners viewed the project as an acceptable loss leader. They wanted to keep referral sources happy and they relied on the unaffected revenue from outside the county and non-bid items. Half the bid winners from Round One of the project found the loss unacceptable as they did not participate in the second round.

Medicare noted key findings in an evaluation report of the Demonstration Project:

1) A non-demonstration supplier had acquired two demonstration suppliers
2) The parent companies of one non-demonstration supplier and one demonstration supplier have filed for bankruptcy. Another demonstration supplier has also filed for bankruptcy protection.

This again demonstrates that even the limited amount of items in the project harmed business.

Regarding the first 10 MSA's, the ability to purchase bid winners led to part of the disaster that followed. As with the demonstration project companies are able bid without any financial accountability and responsibility. In Orlando 14 of the 39 bid winners in Oxygen were located either out of state or over 100 miles outside of the area, without any means to service oxygen patients. For companies out of the area, placing a bid is a no lose situation. Out of area providers place any low bid and if they win they may have a commodity that someone else may willing to buy, like in the demonstration project. A bidder does not need a bond to cover their bid. You don't even have to have subcontract agreements in place proving you can cover a 12 county areas like Dallas before you bid. Then if you win the bid and cannot fulfill your obligation, you can walk away without penalty. However the low price you artificially created is passed on to everyone else.

The Florida Department of Health certified that 9 of the 44 bid winners for oxygen were unlicensed. Our association was informed of this discrepancy when providers contacted Manufacturers representatives of oxygen asking: "How do you get an oxygen license"?
This begs the questions: "How can a company place an accurate bid if they have never provided the service before?" "How can legitimate providers compete when bidders do not bid based on the realities of providing service or equipment?"

Do they employ a Respiratory Therapist at $25 an hour?
How often are they required to visit patients?
Does their warehouse have a quarantine area?
Does their company comply with each county's Comprehensive Emergency Plan?

In order to bid on oxygen, I had to submit the number of patients I serviced with the top three modalities including Liquid Oxygen. This is another determining factor that Medicare never evaluated. Manufacturer's representatives told us that some oxygen bid winners inquired about liquid oxygen after winning the category asking "I won the bid for liquid oxygen and I want to buy some."

A Liquid Oxygen system is 5 times the cost of a standard oxygen concentrator but is reimbursed at the same rate which includes a monthly fill. A few other differences which might change the way you place your bid is that the unit must be refilled minimally once a month no matter how frequently it's used because of evaporation. The cost to refill the system averages half the reimbursement. My company also purchased a truck with a lift gate because the liquid oxygen reservoir weighs 110 pounds. All of these factors would affect a company's ability to place a bid they could honor without going out of business.

When the program was briefly implemented in the first 2 weeks of July, physicians and hospital case managers pleaded with us to continue to accept patients because they went through the published list of

bid winners and could not find a company that could provide liquid oxygen or a respiratory therapist to set up their patient the way they were accustomed to.

This problem was exacerbated by Providers refusing to address patient issues unless their orders were in addition to more expensive reimbursable items. One bid winner in Orlando and Miami sent a letter to all of their participating hospitals and Doctor offices' discharge professionals on April 1st of last year which specifically stated they would "No longer provide: Commodes, and bath safety products", "Canes, Quads Canes and Crutches unless ordered with Oxygen or other DME." If they, a bid winner, will not deliver the item it must be asked who will, and how will a patient be released from a physicians care if discharge professional cannot guarantee proper access to product and service at home.

The lack of transparency in the Interim Final Rules will still create tremendous problems. Medicare said that any unrealistic bids would be thrown out but, Medicare already accepted bids of a 26% cut. The largest Home Medical Equipment provider, Apria Healthcare reported an 8% profit in 2007. How could a company reduce revenue by 26% and survive, when their profit margin is 8%.

Bidders were required to send in tax returns and if those statements were analyzed, Medicare would see that most companies showed a profit of 3% to 5%. By offering bids at a 26% reduction they would be looking at a 21% loss. After winning the bid the average small provider with medicare receivables of a $1 million annually will lose $200,000 a year.

The reduction in companies that currently provide service is astounding, in the Miami MSA for example 402 power mobility device providers was reduced to 18. This would place a tremendous burden on the wheelchair bound, having to locate a limited number of repair facilities and having to deal with backlogs for repairs to the sole device that provides them freedom. There is a reason there are currently over 400 providers, the market demands it. CMS' reduction will in the end harm patients

The most tragic part of these reductions from the program is that when you reduce 501 oxygen providers in South Florida to only 44, you are not only closing businesses and causing unemployment, you are removing an important community resource. In 2005 Hurricane Wilma knocked out power for at least a week in most of the tri-county area of the Miami MSA. Although my company in North Miami Beach lost power for seven days, we never ran out of oxygen tanks or liquid oxygen systems to serve our patients because at the beginning of each Hurricane Season we purchase additional tanks for each patient.

When you reduce 501 oxygen providers to only 44, you would hope that the bid winners are not affected by a storm themselves and have a surplus and facility to house the thousands of tanks they will need to protect their share of the community's patients. In Dallas 4 counties of the 12 in their MSA are without a single oxygen, CPAP or Respiratory Assist Device provider. Dallas has already had 2 ice storms this year that not only knock out power, but immobilized the city because the area is not prepared to de-ice roads and highways.

An AP article explained that "when ice downed electric lines in Epping, N.H., last month, police found 60-year-old Richard Lapoint dead, hooked to his powerless oxygen machine." Fortunately we never had a case like that in Miami, Dallas, Orlando, Pittsburgh, Cleveland, Kansas City and Cincinnati but it is not realistic that with the reduction of providers and counties without providers of oxygen a similar occurrence could happen.

How can a bid winner travel 3 counties away to service a patient.

The reported answer is Sub-contracting, but that is dangerous and is detrimental to patients. Medicare will allow subcontracting, but companies only need to tell Medicare about a subcontract 10 days after they engage in a contract. This means companies can bid, without having negotiated business terms in place. If they cannot find a company with which to subcontract, they can walk away from their bid, after their action forced qualified realistic companies to loose. Subcontractors earn money to meet the needs of businesses in a region, but because they are not the Medicare contracted supplier, their Medicare numbers are not at risk, if they fail to produce or if they harm patients. This for many subcontractors will be free money in the bank, because failure has no repercussions. Most importantly, though, is patient care. Most oxygen patients are very advance in years, consistency and reliability are very important to them, they feel uncomfortable, almost violated if "company A" comes in their home one month and "company B" comes in the next. Providers provide health care, ours is not a delivery service, Patients know this and they rely on that service provider.

Medicare's other argument for Competitive Bidding is that it would reduce the number of providers needed to be policed and managed. Since competitive bidding was introduced in the Balance Budget Act of 1997, new requirements have assured the closure of many providers. A mandatory surety bond is required by all providers by the fall of 2009. Last year a rule was passed that all new companies applying to the DMEPOS program were required to be accredited for 6 months before they could become providers. By the fall of 2009 all DMEPOS providers are required to become accredited. It should also be noted that CMS acknowledges that approximately 28.5% of all Medicare Part B providers will no longer participate in the program as a result of the implementation of the surety bond requirement along with accreditation requirements (CMS-6060-F).

The Competitive Bidding Program reduced the 501 oxygen providers in the South Florida MSA to only 44 bid winners. Since that time, the number of oxygen providers have dropped in the Miami MSA from 501 to now only 423. As companies close, ancillary businesses like the outside billing company that I use based in Boca Raton with 30 employees would close as well. As would local repair centers, distributors, and oxygen refilling services.

Many more providers will not survive the 9.5% cut and the 36 month oxygen cap which began in January. Our new President has spoken eloquently about sacrifice, our industry has been sacrificing for years, but if this program or any fundamentally flawed competitive bidding program proceeds, we will have become "sacrificial lambs" to an old bureaucracy.

President Obama said that he does not want to keep government programs that do not work and intends to expand programs that do. At less than 2% of the Medicare budget, Durable Medical Equipment is the most cost effective program in healthcare. Our services keep patients out of hospitals and rehab centers, so they can live independently in their homes. During this economic crisis we do not want to needlessly close companies, causing more bankruptcies, burden the system with additional unemployment (which will end healthcare benefits), ruin an important community resource called upon during natural disasters and most importantly limit a patient's access to care.

Sincerely Yours,



Robert Brant
President

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June 1, 2008

AMEPA
Accredited Medical Equipment Providers of America

DMEPOS Competitive Bidding Facts – MIAMI MSA (South Florida)

On April 2, 2007 the Centers for Medicare and Medicaid Services (CMS) issued a Final Rule for the Competitive Acquisition Program for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). This controversial Competitive Bidding Program is scheduled to begin on July 1st, 2008 in 10 Metropolitan Statistical Area (MSAs) including Miami. The Miami MSA includes all of Miami-Dade, Broward and Palm Beach Counties. Ten categories of equipment will be affected in the Miami MSA. These items represent the majority of all of the equipment reimbursed by Medicare and includes: Oxygen, CPAP and Respiratory Assist Devices, Standard Motorized Wheelchairs, Complex Rehab Wheelchairs, Enteral Feed & Supplies, Negative Wound Pressure Devices, Walkers, Mail Order Diabetic Testing Supplies, Hospital Beds and Support Surfaces.

Only Accredited providers were allowed to bid. The bidding window ended on September 25, 2007. When the program begins on July 1, 2008, only companies which won the bid may provide equipment to new patients. Of the **501** oxygen providers that are currently in the Miami Competitive Bidding Area (CBA), the Competitive Bidding Implementation Contractor (CBIC) chose to offer contracts to **only 44** companies to provide Oxygen to new and returning patients. Of the **402** Power Mobility Device (PMD) providers in the Miami Competitive Bidding Area (CBA), the Competitive Bidding Implementation Contractor (CBIC) chose to offer contracts to **only 18** companies to provide equipment and services to new and returning patients. The facts enclosed below were compiled from CMS, Industry Media and letters from legislators.

- CMS will reduce the number of Power Mobility Device (PMD) providers in the 3 Counties that make up the Miami MSA (Miami-Dade, Broward and Palm Beach Counties from 402 to only 18 bid winners. That means less than 5% of existing suppliers survived.

- CMS will reduce the number of Oxygen Providers in the 3 Counties that make up the Miami MSA (Miami-Dade, Broward and Palm Beach Counties from 501 to only 44 bid winners. That means less than 9% of existing suppliers survived

- The 457 Oxygen Companies that did not win the bid will not be allowed to provide new orders of Oxygen for Medicare Part B patients after July 1, 2008. This includes patients that have never used oxygen before. Patients that have previously used oxygen that have incurred a 60 day break in service, change of residence out of and then returning into the CBA or changed their Part B status cannot have oxygen provided by non-winning bidders. Non-winning Bidders will be paid the new single payment amount, as all of their existing patients will be grandfathered in. These existing patients will own their equipment after 36 months of continuous rental. It should be noted that these non-winning bidders will lose existing oxygen patients through attrition.

- Industry experts have calculated that the Non-winning bidders which make up 88% of the current Medicare Oxygen providers will most likely close due to the current plan.

- The 457 providers who lost the bid, excludes the Medical Equipment Providers in Monroe and Martin counties which border the Miami MSA. Many of these companies service patients inside the Competitive Bidding Area inside the Miami MSA. These Oxygen providers in counties which border the Miami MSA

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will also not be able to provide Oxygen service to new or returning patients after July 1, 2008. The bidding providers in the bordering counties will certainly be adversely impacted as well

- The economic impact of the projected probable closing of an estimated 91% of the oxygen providers will be devastating to thousands of employees in and around the Miami MSA. They will lose their jobs, lose their health insurance coverage and be very unlikely to find work in this resulting highly job-limited industry.

- Instead of a total of 501 suppliers in the South Florida area, a mere 44 or less than 9% of the current providers will remain to attempt to service the area in the aftermath of he next Hurricane, Tropical Storm or any potential disaster which may affect the area.

- During the weeklong power outages of Hurricane Wilma, the community of providers and the media did not report one instance in which a patient could not receive oxygen service. The local providers had enough back-up oxygen systems, spread out geographically across the area to support their patients during the declared disaster.

- It is highly unlikely that an average of less than 15 oxygen providers per county will be able to provide for the large number of beneficiaries in the area. Particularly if another storm or natural disaster incapacitates any of the bid winning providers

- Medicare's Utilization records show that there were 198,705 Home Oxygen systems (Concentrators-E1390 and Liquid Reservoirs-E0439) allowed as monthly units by the Miami MSAs Medicare Oxygen Providers in 2006. Under the new program, the 44 Oxygen Bid winners will be responsible for the service and maintenance of all of those existing Oxygen patients. That is an average of over 4,500 oxygen providers per bid winner annually, once the current rental period ends.

- It has been reported that some Oxygen Bid winners have never provided oxygen before and are unaware of the demanding requirements and licensure required to dispense this type of drug. These companies may be accredited to provide walkers, but they are not accredited to provide oxygen and are not aware of the policies and procedures for training, delivery, testing, servicing and maintenance requirements to provide oxygen.

- CBIC has also been questioned by legislators for allegedly misplacing required application documents. As a result CBIC appears to have erroneously disqualified hundreds of bidders which may have won the bids and affected the overall new reimbursement. The majority of these Disqualified providers and bid losers are small businesses. Medicare has estimated that small businesses make up 90% of all providers prior to the bid.

- All available evidence supports the conclusion by industry experts that the geriatric, Medicare populace will suffer greatly as a result of the new Rules. Instead of the personalized service they receive now, patients will be forced to solve their problems through the use of automated phone systems, voicemail, call back options, and endure the frustration of long wait times both for answers and deliveries of services and equipment

- Healthcare providers believe that patients will have a difficult time receiving portable oxygen once the program begins as a result of the new reimbursement which has been reduced to only $22.68 per month in the Miami MSA. The figure of $22.68 includes the cost to deliver as many tanks as the patient needs per month. Delivery costs on a single monthly delivery, exceeds the proposed reimbursement. Furthermore, substantially reduced Medicare payments on all other items, eliminates the supplier's ability to cover losses in one area with net income in another.

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- The servicing of Oxygen patients will be even more complicated and financially disadvantageous starting January 1st, 2009. At which date all of the patients who have been using Oxygen prior to and since January 1, 2006, will become owners of their Oxygen equipment.

- Oxygen was always paid for monthly for as long as it was medically necessary for the patient to use it. Now the patient owns the oxygen system after 36 months.

- In the Miami MSA the rental payment by Medicare for oxygen will be reduced to less than $140.00 per month. That monthly reimbursement includes the cost of filters, tubing, cannulas, oxygen masks, humidifiers, patient retraining, maintenance and any necessary replacement of the equipment.

- After January 1, 2009, when the patient owns their oxygen system, the bid winners will only receive a few dollars for the cost of replacement supplies and cannot bill for the travel time to and from the patients residence. It is obvious to suppliers that costs will substantially exceed reimbursements

- Therefore industry experts feel that, as a necessity for survival of the winning bid suppliers, the service and maintenance of the patient's Oxygen systems will be unavoidably severely neglected. They feel that repairs and maintenance of the systems will be very hard for patients to receive, especially by patients who own their systems after January 1, 2009.

- Today companies compete to have Oxygen repaired within a few hours and by providing service 24 hours a day, as quickly as possible to keep their patients happy.

- There are no specific time requirements in the current Medicare Supplier Standards or in the Competitive Bidding Program for the delivery, repair or servicing of Oxygen equipment. In the past that did not matter, because reimbursement was sufficient to allow suppliers to compete on the basis of the speed and efficiency with which they provided these services. That will no longer be true.

- After the Competitive Bidding Program begins, it will be very difficult for a patient to change their provider for any reason, whether valid or not.

- Industry experts believe that after the program begins, the larger companies will purchase the smaller ones and the few remaining companies will have a monopoly.

- When the monopolies occur, every community will lose virtually all its local suppliers. As a result, in addition to the serious deterioration of services to insured patients, uninsured patients and patients with limited medical equipment coverage will pay higher retail prices from the remaining providers.

- The patient's access to care and services are already being affected in the 10 MSAs. Bid winners have already sent information to Hospital Discharge Planners, Case Managers and Doctors explaining that they will no longer deliver Bedside Commodes and other less expensive equipment if it is not accompanied with an oxygen order. Before the bid, providers would provide these less expensive items in order to compete in the market as a "one stop shop".

- With such low margins, bid winners do not have to provide services that the community took for granted such as a timely response or even delivery. This is another example of how this program will affect patients, as the remaining providers will not provide services that they have not won or are no longer profitable. Patients will be forced to either travel outside of their area to obtain home medical equipment or pay a high cost for delivery which they never had to in the past. Unfortunately it is more likely that the patient will not go through the extra cost or hassle to get the equipment they need. This will cause more incidents of home slip and falls, poor patient outcomes and eventual greater costs to the entire Medicare system.

Disclaimer: The information on this document is believed to be accurate. However those who read it should not act upon it until they have satisfied themselves, from their own independent sources of the accuracy of the information provided.

Accredited Medical Equipment Providers of America
20815 N.E. 16th Avenue – Suite B-32 • Miami, FL 33179 • 305/654-5957 • Fax 1-866-322-2060 • www.amepa.us

Rob Brant

From: Rebecca_Burnett@doh.state.fl.us
Sent: Tuesday, June 17, 2008 8:40 AM
To: rob@citymedical.com
Subject: RE: Please verify that the following companies do not have Medical Oxygen Retailer Licenses

Good Morning Mr. Brant,

The companies listed are not currently licensed as Medical Oxygen Retail establishments with the Florida Department of Health, Drugs, Devices, and Cosmetics Program.

Rebecca

From: Rob Brant [mailto:rob@citymedical.com]
Sent: Thursday, June 12, 2008 1:21 PM
To: Burnett, Rebecca J
Subject: Please verify that the following companies do not have Medical Oxygen Retailer Licenses

To: Rebecca Burnett – Regulatory Specialist, Florida Department of Health
From: Rob Brant, AMEPA - President

Dear Ms. Burnett

On behalf of the members of the Accredited Medical Equipment Providers of America (AMEPA), I wanted to thank you for taking the time to resolve the very important issue of proper Medical Oxygen Retailer Licensure.

As we discussed earlier, there is a new Medicare Competitive Bidding in Home Medical Equipment which is scheduled to begin on July 1, 2008. The program will be implemented in the South Florida Counties of Miami-Dade, Broward and Palm Beach (Miami MSA) and also the Central Florida Counties of Lake, Orange, Osceola and Seminole (Orlando MSA).

Once the program begins, only Bid Contract Winners may provide new oxygen service to Medicare Part B Beneficiaries in those affected areas. That is why it is very important that we verify if Bid Winning Companies have Medical Oxygen Retailer's Licenses or have the appropriate Pharmacy License in order to dispense oxygen.

According to the Florida Department of Health's Search Website, the following companies do not have Medical Retailer Oxygen Licenses and are not Pharmacies:

1) Bestcare Medical, Inc. – Orlando, FL
2) D & E Supplies, LLC – Sunrise, FL
3) Easy Life Medical Supply, Inc. – Hollywood, FL
4) HEB Homecare, Inc – Hurst, TX
5) Home Medical Equipment of Fort Worth – Richardson, TX
6) Plus Medical, LLC – Delray Beach, FL
7) PRO2 Respiratory Services, LLC – Cincinnati, OH
8) Scooter Store – Boca Raton, FL

Casselberry, FL
Jacksonville, FL
Orlando, FL

9) Super Care, Inc. – City of Industry, CA

Please reply if the Florida Department of Health's Search Website is current and up to date.

Please respond as quickly as possible. The companies that are listed above are already listed on Medicare's Website as the Oxygen Bid Winners

Very Truly Yours,

Rob Brant
President

Accredited Medical Equipment Providers of America, Inc.
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Miami, FL 33179
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O – 305-654-5957
F – 1-866-322-2060
rob@amepa.us

No virus found in this outgoing message.
Checked by AVG.
Version: 7.5.524 / Virus Database: 270.2.0/1497 - Release Date: 6/11/2008 8:32 AM

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Version: 7.5.524 / Virus Database: 270.3.0/1499 - Release Date: 6/12/2008 7:13 AM

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Version: 7.5.524 / Virus Database: 270.3.0/1505 - Release Date: 6/16/2008 7:20 AM

FLORIDA DEPARTMENT OF HEALTH

Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
Secretary of Health

July 12, 2007

City Medical Services, Inc
20815 NE 16 Ave, #B-34
N. Miami Beach, Fl 33179

Dear Administrator,
Thank you for the submission of your agency's Comprehensive Emergency Management Plan (CEMP) Your plan has been reviewed and meets the basic criteria established by Florida Administrative Code (FAC).

It is your agency's responsibility to review your plan annually. When there are changes, please include a completed criteria form on which such changes are highlighted. Your reviews must be completed annually from the date of this letter.

Please note a copy of this approval letter along with your CEMP will be retained by the county health department in the county in which you are licensed.

If you have questions or concerns, please call the Office of Public Health Preparedness. at (786) 845-0226.

Sincerely,
Myra C Markowski
Cemp reviewer and
Special Need Coord
MIAMI DADE COUNTY
HEALTH DEPARTMENT

Miami-Dade County Health Department
8175 NW 12 Street, #300, Miami, Florida 33126
Tel: (786) 845-0226 Fax: (786) 845-0109
Website: www.dadehealth.org

Natarajan Rajagopalan MD, MRCP, FRCP(C), FCCP
Board certified

Internal Medicine
Pulmonology

Critical Care Medicine
Sleep Medicine

9618 Pines Boulevard
Pembroke Pines FL 33024
Phone: 954 450 4511

21000 NE 28th Avenue Suite 203B
Aventura FL 33180
Fax: 954 450 4561

July 3, 2008

United States Senator Bill Nelson
Washington, DC 20510

Dear Senator Nelson,

As the Chief of Staff at Aventura Hospital in Miami-Dade County, I am writing to stop the Competitive Bidding Program in Durable Medical Equipment, Prosthetics and Orthotics (DMEPOS) which began on July 1st.

None of the accredited DMEPOS companies that my staff has been working with for over ten years won bids. I instructed my staff to work with the list of bid winners as instructed and provided by the Center for Medicare Services, CMS. In over ten years working in the South Florida area I have never heard of these companies before.

Yesterday, an order was placed for liquid oxygen for a patient on a high liter flow. Typically the equipment is delivered by a Licensed Respiratory Therapist, who reports back to the discharging Pulmonologist or Critical Care Physician. We found that none of the companies we called carry liquid oxygen systems. I found out that with the goal of finding the lowest bidder companies can sub-contract specialized oxygen services through un-accredited companies. They are not required to have the equipment set-up by or have the patient trained or evaluated by a Respiratory Therapist.

In one case, my office manager placed a call with a bid winner before noon for oxygen equipment. She was told that the equipment could be delivered tomorrow or the next day. Typically oxygen is delivered to a patient in hours not days. That policy will create countless problems for Aventura Hospital and the other Hospital in the area. We cannot wait days for equipment to be delivered to the hospital or to the patient's home before they are discharged. The hospital needs the patient's room and we are unable to bill Medicare additional days for a hospital stay.

I have included a letter our case mangers received back in April from a bid winner. The letter states that the company refuses to deliver commodes, crutches or canes (non bid items) if the order is not placed with oxygen or other rented equipment. If a patient needs to be discharged with only a quad cane and a commode without oxygen, how is the patient going to get the equipment if the few bid winners are refusing to provide this medically necessary equipment because they no longer have to compete in the marketplace?

In the past local providers competed for our business by working with case mangers to help us with these sensitive issues. Today the lowest bid is costing the hospital in the form of increased hours by case managers, juggling multiple bid winners trying to coordinate the discharge of a single patient. If a patient requires a hospital bed, walker, enteral tube feeding, therapeutic ventilation and oxygen case managers may have to coordinate with 5 separate bid winners to get the patient home.

Fortunately the program is only days old and the damage is minimum but if it continues throughout Hurricane season it will be disastrous. Nine bid winners do not have Oxygen Licenses and cannot purchase gaseous or liquid oxygen. They will be relied on while other companies close.

For these reasons and more, I again ask that you stop this program which will cost South Florida Hospitals untold millions.

Sincerely,

Natarajan Rajagopalan, M.D., MRCP, FRCP(C), FCCP

PULMOCAIR

Competitive Bidding Facts

- Competitive Bidding goes into effect July 1, 2008 in the first 10 MSA's. In 2009 it will affect 70 more MSA's
- Patient choice of suppliers will be severely decreased
- Access to quality brand name products will cease to exist
- Ingenuity and Research and Development for better products will decline
- Thousands of small companies will go out of business and thousands of workers will be laid off
- DME companies will be forced to cut programs and services provided to beneficiaries

Pulmocair won in the following product categories

- Oxygen and oxygen equipment
- Standard power wheelchairs, scooters and related accessories
- Mail-order diabetic supplies
- Enteral nutrients, supplies and equipment
- Continuous Positive Airway Pressure devices, respiratory assist devices and related supplies and accessories
- Hospital beds and related accessories
- Negative pressure wound therapy pumps and related supplies and accessories

Pulmocair lost the following product categories

- Walkers and related accessories
- Support surfaces, such as specialized mattresses to help people with pressure ulcers

As of April 1, 2008 Pulmocair will no longer provide:

- Walkers, unless privately purchased
- Commodes and Bath Safety products, unless ordered with Oxygen or other DME
- Canes, Quad Canes, and Crutches unless ordered with Oxygen or other DME
- Group II Support Surfaces, unless privately rented or purchased

As of April 1, 2008 Pulmocair Policy Changes

- All orders will be scheduled for next day delivery, except Oxygen, Nebulizers, and RT Evals or Pulse Oximetries
- Respiratory Medications will be delivered next day by Pulmocair. If medications are required same day, Pulmocair can transfer a prescription to the patient's local retail pharmacy for the patient to pick up. Monthly reorders will continue to be provided through Pulmocair's mail order pharmacy.
- All Oxygen orders must be accompanied by qualified results. If results are not available, Pulmocair will arrange for oximetry testing in the home prior to delivery of oxygen. Once the patient is tested and qualifies per Medicare guidelines, then the oxygen equipment will be delivered and the patient will be seen by a Respiratory Therapist.

Between now and July 1, 2008 we want to help you maintain order and reduce confusion for your patients. We ask that when placing orders for any Competitive Bid items please ask your current DME provider which products they won the contracts for. If you refer a patient to a non winning supplier for a Competitive Bid product you may have a service problem in the future as they may not be in business to service the patient when needed.

To close, we at Pulmocair have been serving the needs of the medical community for 10 years. During that time we have endured many challenges and Competitive Bidding is just the latest. We have always strived to provide our patients and our referral sources with the highest level of quality care. You have our word that we will do everything in our power to maintain a level of service that you can be proud of. Thank you for your continued support!

Sincerely,

Kyle Miko

Kyle Miko, RCP Founder and Vice President

Jon Fedele

Jon Fedele, Founder and President

Out of area Oxygen Bid Winners for Orlando

Companies were awarded bids without a physical location in Orlando
16 of the 39 Bid Winners were located over an hour outside of Orlando or out of state
14 of the 39 Bid Winners were located over 100 miles outside of Orlando or out of state



Out of State Bid Winners

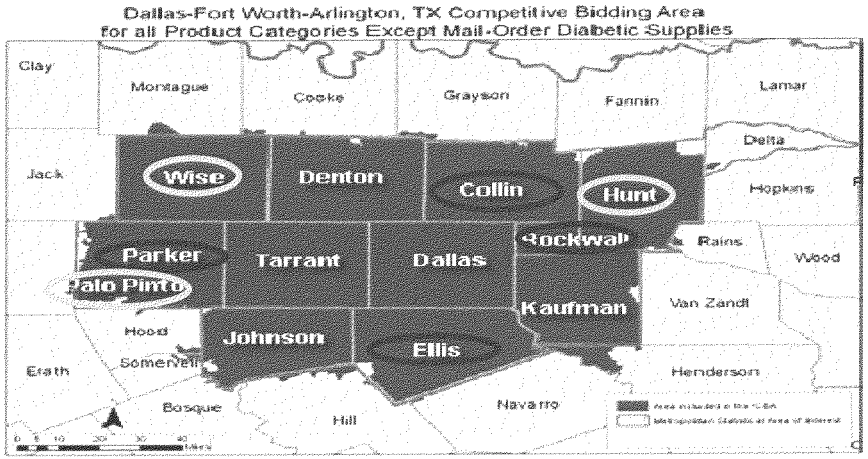
Hurst, Texas
Richardson, Texas
City of Industry, California

None of theses companies had state licenses to provide oxygen

Disclaimer: This map was created by the Accredited Medical Equipment Providers of America. The cities listed corresponds with a list of Oxygen Bid Winners for Orlando in the Competitive Bidding Program for Durable Medical Equipment, which was set to begin on July 1, 2008. The 16 cities were from the list of 39 Oxygen Bid Winners for Orlando. The list was posted on the Center for Medicare and Medicaid Services' website (www.medicre.gov) in May of 2008. The background of the map was provided by geology.com.

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Dallas Oxygen Providers - 284 Current Providers reduced to 35 Bid Winners
Dallas CPAP & Respiratory Assist Providers - Reduced to 25 Winners, 11 are either out of state or hours outside of the area



Hunt, Palo Pinto and Wise Counties have One (1) "Bid Winner" for Oxygen and CPAP & Respiratory Assist Devices.

Collin, Ellis, Parker and Rockwall Counties DO NOT have an Oxygen or a CPAP & Respiratory Assist Device Provider. There is no hospital in Rockwall County

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AMEPA

Total Percentage of Top 20 DMEPOS Groups affected by the Round One Rebid

Rank	Policy Group	Items in Round 1 Rebid	CY 2003	Percent of Top 20 Groups
1	Oxygen Supplies/Equipment	X	$2,433,713,269	31.0%
2	Wheelchairs/Power Operated Vehicle (POVs)**	X	$1,926,210,675	24.6%
3	Diabetic Supplies & Equipment	X	$1,110,934,736	14.1%
4	Enteral Nutrition	X	$676,122,703	8.6%
5	Hospital Beds/Accessories	X	$373,973,207	4.8%
6	CPAP Devices	X	$204,774,837	2.6%
7	Support Surfaces	X Miami	$193,659,248	2.5%
8	Infusion Pumps & Related Drugs		$149,208,088	
9	Respiratory Assist Devices	X	$133,645,918	1.7%
10	Lower Limb Orthoses*		$122,813,555	
11	Nebulizers*		$98,951,212	
12	Walkers	X	$96,654,035	1.2%
13	Negative Pressure wound therapy (NPWT) Devices		$88,530,828	
14	Commodes/Bed Pans/Urinals		$42,890,761	
15	Ventilators		$42,890,761	
16	Spinal Orthoses*		$40,731,646	
17	Upper Limb Orthoses*		$29,069,027	
18	Patient Lifts		$26,551,310	
19	Seat Lift Mechanisms		$15,318,552	
20	TENS Devices**		$15,258,579	
Total for 20 Groups in DMEPOS			$7,830,384,538	
Total Percentage of Top 20 Groups affected by the Round One Rebid				91.1%

NATIONAL ASSOCIATION OF INDEPENDENT MEDICAL EQUIPMENT SUPPLIERS
5037 Halifax Road, Suite L7, P. O. Box 669
Halifax, Virginia 24558

434-572-9457 — FAX 434-572-6889
TOLL FREE 1-866-4DMEHELP
www.dmehelp.org e-mail – yourfuture@dmehelp.org

Testimony Of Wayne E. Stanfield
President and CEO of the
National Association of Independent Medical Equipment Suppliers (NAIMES)
On behalf of its Members

Before the House Small Business Sub-Committee
On Rural and Urban Entrepreneurship

February 11, 2009 at 10:00 am

Summary Statement

Chairman Shuler, Ranking Member Luetkemeyer, members of the Committee, my name is Wayne Stanfield and I am President and CEO of the National Association of Independent Medical Equipment Suppliers (NAIMES). We are a trade association representing and supporting the independent durable medical equipment (DME) supplier community. I am also a partner in an independent DME supplier, Carolina Med-Plus, Inc that is in the Round One Charlotte, NC CBA. We participated in the bid process last year but did not win a contract because we were above the pivotal bid.

NAIMES commends this Subcommittee for examining the impact of CMS's competitive bidding program for DME on small suppliers, which will be profound. Competitive bidding for DME was a part of the Medicare Modernization Act of 2003 and while the stated purpose was to save Medicare money, that contention gave no consideration to the service to patients, and the impact on small businesses, communities, and employment. CMS contends that DME competitive bidding represents a "market-based efficiency." I respectfully submit that this program does not represent anything close to healthy market economics.

Competitive bidding makes perfect sense for a multi-million dollar aerial tanker replacement for the Air Force, but makes no sense at all for an $89 walker or life sustaining oxygen services for a senior citizen. Competitive bidding has no place in healthcare and will result in higher costs to Medicare, lower quality products and less access to needed services by Medicare beneficiaries.

Competitive bidding is an exclusionary process. It is important to understand the gravity of this assault on small business in America. Since the vast majority of HME providers are small and independently owned, it stands to reason that they will bear the brunt of the burden.

According to CMS figures from 2007, there are 110,272 supplier numbers billing Medicare and of those 103,227 bill Medicare less than $300,000 per year. That is 94% of the total suppliers. It is also important to note that despite new start-up businesses in the DME industry, there was a decrease of more than 4,000 suppliers from 2006 to 2007. Also notable is that in the cancelled first round, winning bids in the 10 bid areas represented less than 10% of the total supplier numbers active in those localities, meaning 90% of the suppliers were excluded from the Medicare marketplace in their own communities.

These small businesses are a major part of the engine of the American free enterprise system. They employ more than 1.5 million people while serving over 50 million Medicare, Medicaid, and private insurance patients each year. These businesses help keep patients out of institutional settings and at home where not only do they prefer to be, but is the least costly alternative for everyone.

The DME segment of Medicare is historically less than 2% of the total Medicare budget and in spite of the growth in the Medicare population, has been virtually flat in growth of expenditures decades. Yet, this smallest segment of Medicare expenditures is repeatedly singled out for fee cuts, competitive bidding, and other measures such as surety bonds, all of which are forcing businesses to close or stop serving Medicare patients. Homecare and DME should be growing since the cost of this care is infinitely less expensive than a hospital or nursing home. According to a recent market study by the Freedonia Group, the need for medical equipment will grow by about 5.5% through 2012, primarily due to the rising number of older Americans. A program that reduces suppliers at a time when demand is increasing simply defies logic.

It has been acknowledged by CMS and industry experts that the competitive bidding process, when complete, will eliminate up to 90% of these businesses from the Medicare provider rolls. Should this happen, it will be devastating to this supplier community, as well as severely limiting access to medical equipment for Medicare beneficiaries. The remaining suppliers will not be able to meet the demand created by the growing Medicare population. As the baby boomers age, every day an average of 7,918 people will be added to the Medicare roles. For the DME industry this means a growing market. Under a free-market economic theory, this will mean that more competitors will be entering this market, helping to drive down or stabilize prices in the face of increasing demand. Competitive bidding will have the opposite effect.

This government-sponsored program will eliminate competition by dismantling a national network of suppliers that have reliably serviced the home health needs of Medicare patients for decades. While CMS has developed this program and has released the final rules for its re-implementation, it is Congress that authorized CMS to pursue this unworkable program. It is inconceivable that it would be our government that would promote a scheme to concentrate market share and eliminate competition at such a crucial time for our economy. This is a formula for higher prices over time and is bad public policy that must be ended now.

NAIMES strongly opposes the re-implementation of this flawed program and recommends that Congress repeal the applicable portions of the Medicare Modernization Act of 2003 as soon as possible. Much of the anticipated savings have already been realized through previously instituted reimbursement cuts, such as the FEHBP cuts in 2007, the elimination of

CPI increases for DME services for more than 5 years, and the devastating 9.5% cut on fees for bid products effective at the beginning of 2009.

I urge this Subcommittee to support the repeal of competitive bidding and return the free enterprise system to the small independently owned DME providers and allow them to meet the needs of America's aging population.

Thank you Chairman Shuler for this opportunity to testify before this Committee today.

Additional comments in conjunction with my testimony at the hearing held by the House Small Business Sub-Committee on Rural and Urban Entrepreneurship on February 11, 2009

The **National Association of Independent Medical Equipment Suppliers (NAIMES)** strongly urges Congress to immediately suspend the pending restart of Round One of the Medicare competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and ultimately repeal the provisions of the Medicare Modernization Act of 2003 (MMA03) establishing this program.

This flawed program is bad public policy and will neither save money for Medicare, nor achieve its goal to reduce DMEPOS fraud and abuse. A program of patient care based on the lowest bid will create a two-tiered system for DMEPOS and restrict patient access to care. The statute also unconstitutionally eliminates due process for participating suppliers by waiving federal acquisition regulations and removes all administrative and judicial review.

In July 2005, despite the outcry from Congress and the public, the Centers for Medicare and Medicaid Services (CMS) began implementing the program in the first 10 of 80 areas of the country in July 2008. Although ultimately delayed at a tremendous cost to providers, CMS is now set to restart the program without making substantial changes to the rules. Reports clearly showed that there were serious problems with the program during the 15 days it was in effect.

Although Congress made changes with the passage of the Medicare Improvements and Patient Protection Act of 2008 (MIPPA) designed to address some of the concerns raised by the supplier community, fundamentally the program remains intact and still has most of the same concerns. With the procedural flaws, operational problems and other irregularities that have repeatedly been brought to the attention of CMS, it is clear that there are serious problems in the manner in which competitive bidding is being implemented and the fairness of the overall process. The same problems of transparency and inadequate procedural controls exists as CMS now restarts the program without significant changes. Congress must now exercise proper oversight and repeal competitive bidding before grievous harm is caused to millions of beneficiaries and tens of thousands of small businesses. It is clear that the intent of Congress will not be met by this program; and it threatens the financial viability of a large number of qualified and accredited DME suppliers as well as the future of the entire homecare industry.

One of the most critical issues with competitive bidding is the apathetic lack of understanding of how the DME industry connets with other healthcare providers and functions. The DME supplier community is made up of providers who serve a local service area, sometimes as small as few miles in any area. In most cases, these service areas are literally a community, particularly in large metropolitan areas. The bidding process of requiring a bid winner to serve the entire competitive bidding area (CBA) is in itself exclusionary. An accredited provider serving the western most part of the Riverside, California CBA would find it physically impossible to serve the easternmost area 120 miles away. Expecting that same supplier to subcontract in order to stay in business would require business expertise far beyond the abilities of most small businesses.

Another serious problem with the bidding program occurred with the start of round one in July of 2008. Referral sources were unable to find suppliers who could provide equipment to their patients. Sometimes a physician's staff would have to call 4 or 5 suppliers to get the same services they were ordering before for a local supplier they knew and trusted to care for their patients. Often when a supplier was located, there was a delay of several days to obtain equipment due to either the distance the contracted supplier had to travel, or the equipment would be shipped by UPS to the patient. This caused additional cost to the Medicare program in many cases because a patient was not able to be discharged because equipment was not available.

Suppliers who were not selected for a contract were contacted by a bid winner who did not have a presence in the local area and offered a contract. In numerous cases, the non-contract supplier was told that they would be paid 80% of the contract fee to handle all aspect of the service except billing. In most of those cases, the bid winner told the subcontractor they would not be paid until after the bid winner was paid. There were cases where an oxygen provider with one location in one CBA won a contract for 8 of the 10 CBAs with no ability to serve the areas thousands of miles away.

In all of the CBAs, there were bid winners in equipment categories where the winner had no experience, and no qualified staff to perform the service. Often these bid winners bid low expecting to win with the sole purpose of making "a fortune" by finding subcontractors to do the work. They were then left unable to serve the patient's needs because the fees were too low for any subcontractor to accept the patient. In one case a pharmacy won a bid for power wheelchairs and has never provided power mobility before.

Other suppliers bid to win with the intent to seek a buyer for their company if they were awarded a contract, despite CMS rules that placed restrictions on such transfers of ownership.

It is clear that this entire program is flawed and if implemented would result in serious harm to small suppliers and create a situation where the needs of the Medicare beneficiaries would not be met. All of the studies related to the competitive bidding program, including the independent Drexel study published in 2007, supports the industry's view that competitive bidding as designed would not function as CMS expected and would be anti-competitive. The Robert Morris University study and the Drexel study show clearly that this program is in fact not competitive bidding at all.

Statement from the Drexel Study conclusion:

> The problem with the CMS process is that the bid scoring and price formulation procedures are inconsistent with the bidding behavior that CMS wishes to induce. That is, overly complex rules for choosing winners and setting prices distort the incentives that bidders face and may actually result in increased prices for some consumers. We believe that the misalignment of the rules with the desired bidding behavior stems from a faulty application of single-unit auction results to a multi-unit setting: a misconception that has even been propagated by Nobel Laureates (see Ausubel and Cramton 2002, pp. 1, 27, for a discussion).

Conclusion from Robert Morris Study:

> In short, the proposed competitive bidding for medical equipment and supplies will increase concentration and will reduce competition. Medicare already regulates price and, if price is truly too high, could reduce it. This leaves us to ask, what will we gain from competitive bidding? Administrative convenience or capture, appear to be the only justifiable reasons. There may be a short run advantage to CMS if successful bidders are willing to cut price (or pay a premium) to gain market power, and it may be easier to regulate fewer firms. However, in the long run the bidding scheme will have traded a competitive market for government-

mandated concentrated market. As a result, we will have traded small short run benefits for major long run problems – poor public policy indeed.

It should also be noted that CMS has ample authority to adjust prices to meet market demands without implementing such a program. The concept of this misguided program came about because the creators did not understand the DME industry and how the network of over 100,000 suppliers has been woven into the fabric of healthcare in virtually every community. The businesses, small and large, live and work in neighborhoods where it is literally, "neighbors serving neighbors". It is not possible to move away from that concept without harming everyone involved, including the patient, the physician, and every other component of healthcare that touches that patient.

The following problems and concerns with the original start of Round One have been identified by NAIMES.

1. Hundreds of suppliers were improperly disqualified based on errors and unsubstantiated reasons, indicating mistakes and flaws in how CMS managed the selection process.

2. CMS changed the program rules without notifying bidders. There is no indication that the revised implementation rules are any more transparent.

3. Based on CMS figures, more than 1000 suppliers were excluded from the original start in Round One areas. There were approximately 300 bid winning companies to serve all beneficiaries in the bid categories in the first 10 competitive bid areas (CBA). There is no indication in the newly released final rule that changes this outcome.

4. Suppliers who had no presence in a geographical region were awarded contracts. Suppliers were offered contracts to serve all regions without having any viable plan to do so and without any subcontracts with other suppliers to serve bid areas for them. CMS used no mechanism to verify a supplier's ability to meet the bid criteria. Despite the mandate in HR 6331, the new final rule does not clearly rule out this happening again.

5. Suppliers were offered contracts to provide product categories that they have never provided before. CMS did not verify that a supplier was experienced in a product category even though there was claims history available from the DME Medicare carriers.

6. The bid process and criteria used by CMS allowed suppliers to submit a bid without proving their ability to perform under the contract. Most of the information submitted was subjective without any appropriate means for CMS to verify its accuracy.

7. The online bidding software program was fraught with problems and errors as well as being so un-user friendly that undetected errors could be made. Despite claims that this has been resolved, there has be no details provided to prove it.

8. Bid prices were extremely low, resulting in a low median price. Many suppliers bid purely to insure they would be included rather than understanding that such unsustainable low bids would harm all bid winners.

9. Due to the elimination of due process in the statute, and the subsequent shroud of secrecy, CMS refused to share meaningful data to allow a third party to assess the likely impact of the program on suppliers and beneficiaries. This is in stark contrast to customary standards of government

transparency. The new final rule does little to change this problem and due process can only be restored by Congressional action.

10. The flawed bidding process set a pivotal bid based on capacity that was not validated by CMS. This resulted in only the lowest bidder's prices being included in the final median fee calculation. This set the new fee schedule lower than suppliers can operate and still remain financially sound. All of the studies related to this program noted that this process of setting the bid amount was seriously flawed.

11. The contract offered by CMS allowed no recourse for a supplier that accepts the bid offer and then finds they are unable to meet the terms of the contract. The only way out of the contract is for CMS to terminate it for breach of contract. This indicates the only escape for a supplier is to go out of business.

12. Contract language indicated that breach of contract can result in the loss of the bidder's supplier number. Failure to meet the bid criteria would eliminate a supplier from the Medicare program completely, even though they can still supply non-bid products in the area. This is an uncommon and counterproductive business practice in any marketplace and unjustly penalizes a supplier who accepts the contact without knowing the consequences.

13. Winning suppliers have no guarantee of any new business since larger companies could capture market share by using their substantial resources to promote their businesses.

14. Physicians contacted by NAIMES have grave concerns about their patients under this program. With their usual list of preferred suppliers reduced by as much as 90%, many are concerned for the well-being of their patients after implementation. In the original start of Round One in July 2008, CMS failed to adequately notify hospitals, physicians, and other healthcare professionals about the changes.

15. CMS failed to provide adequate notice or information to those being affected. By the time bid winners were formally announced, there was less than 60 days to complete the requisite community education of this untried, unproven program filled with many unintended consequences.

16. The Program Advisory and Oversight Committee (PAOC) was created as a part of the bidding program. The purpose of this committee was to advise CMS on issues and concerns in order to make the program better. Despite the many concerns raised as the program was developed, few of the recommendation of the PAOC were used by CMS. Virtually all of the problems that came to light after the bidding process was launched were addressed by the PAOC committee.

NAIMES is very concerned about competitive bidding and will work with members of Congress to help meet the stated goals for this program following repeal. NAIMES can offer alternatives that will both reduce fraud and abuse, and reduce program costs by applying realistic solutions.

NAIMES cannot emphasize strongly enough the importance of STOPPING this program and urges Congress to immediately suspend re-implementation while working to repeal these provisions this flawed program.



GRIFFIN HOME HEALTH CARE, INC

House Committee on Small Business

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

February 11, 2009

Testimony of Mr. William H. (Bill) Griffin
President/CEO Griffin Home Health Care, Inc
Charlotte, NC

On behalf of the

North Carolina Association for Medical Equipment Services

Testimony
of
Griffin Home Health Care, Inc.
before the
Committee for Small Business
of the
U.S. House of Representatives

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

February 11, 2009
10:00 AM

Good morning Mr. Chairman and distinguished members of the Subcommittee. My name is Bill Griffin. I am President/CEO of Griffin Home Health Care in Charlotte North Carolina. I am very honored to have this opportunity to speak to you. Thank you!

I founded the company in 1983 in the corner of a small independent drug store out of a very strong desire to be of service for my fellowman, which is my own personal mission in life. At the time I started the business, there was primarily one provider of medical equipment and supplies in the market place and they did not accept Medicare or insurance assignment. That certainly opened doors and created a niche for my firm. My background had been funeral service and retail pharmacy. I had learned much about taking care of patients and families and having compassion for others. Consequently, I brought these characteristics with me into the medical equipment industry and therefore we have taken great pride in serving our clients and their needs.

I have personally been active in State and National Concerns of the Durable Medical Equipment Industry (DME). I worked very closely with the NC Department of Health and Human Services to reduce the spending for DME by over 10 million dollars. While serving as President of our State Association, I helped our state to clarify and implement the Sales Tax laws for our industry and worked with the State Attorney General to interrupt the laws governing "bedding." During my time as president of the NC Association for Medical Equipment Services, we hosted Congressional Receptions for our State Delegation. I served on the House of Delegates for our National Association and most recently on the DME/RT Council of AA Homecare. I have walked the halls of the Congressional Office Buildings, visited with Senator Richard Burr on several occasions, Senator Dole, Representative Myrick, Hayes, Price, Watt, and others. In other words, I have a passion for not only the industry but also the clients we serve.

The DME Providers of North Carolina were the very first in the Nation to push for and help to require licensure for our industry. We did this as providers to proactively provide safety and quality to the patients being served and to help maintain very high standards for our providers. At the current time CMS reports that 38 states require Oxygen Providers to be licensed. We as an Industry in North Carolina have been very supportive of Respiratory Care Practices in assuring that providers are licensed and providing ethical and caring services to the residents of North Carolina.

I am proud of my accomplishments as an individual but greater still I'm proud of our state and our industry. Certainly the DME Industry provides a vital part for the care of the individuals in our health care system. It is very important to understand that the DME Medicare Benefits are less than 2% of the total Medicare Budget. Much of that is a result of Small Business. The owners of these small to medium size businesses are the individuals that you see at the Rotary Club Meetings; these are the people with whom you serve on committees at the local churches and synagogues; they provide the care to the mothers, grandparents, and family members of those we know and see at the local PTA Meetings.

Mr. Chairman and Committee Members, there is no debate that our health care system is broken and in need of major overhaul. Competition in its purest form is very healthy. Competition keeps businesses honest; service oriented, and ultimately keeps prices competitive. My impression is that CMS wants to eliminate competition by eliminating DME providers of which many are small businesses. I don't have to remind you that Small Business is the backbone of this Country and generates many jobs.

Being in Charlotte, my company was in the first round to bid or compete in the National Competitive Bidding Process. The process in itself was antiquated and very cumbersome to say the least. We bid for 5 out of the 10 categories and unfortunately or fortunately did not win a single product category. The information I received from the NCB Contractor was that our bid prices were too high. Why? Because I looked at my overhead and schooled myself very carefully before committing to prices that would only allow substandard service, poor quality products, and ultimately "drive us in the ground." There are many troubling issues surrounding the fact that we as a "stellar" organization had a local presence for over 25 years, serving patients and clients and now would be unable to continue providing those services. The fact that we were told that our prices were too high is a very clear indication that many provider/suppliers "bid to win" rather than bid so as to fulfill the commitment of the bid contract. Let me share with you; The DME Industry is a *Service Industry*! It is not a commodity. It is virtually impossible to place a price on or bid on the value of added services that are provided while delivering a hospital bed, setting up oxygen in the home, or assisting a patient with a Sleep Apnea machine. I've been in business for a

long time and I was very careful, methodical, & analytical to compile a bid that I could work with, live with, and stay in business.

I'd like to share just a few of the troubling issues:

Many of the Bid Winners had No physical Presence in the local Communities like Charlotte. CMS awarded these Bid Contracts to providers who were not even licensed in the State of North Carolina.

Inexperienced and under capitalized companies were awarded winning bids. Several of the bid winners are young companies, some 2-4 years in existence. Many of the Bid Winners had never provided services for the winning product categories, were not licensed nor accredited for winning categories, which was a requirement from CMS.

Many businesses will close their doors. One industry expert calculated that only 9% are going to win the bid. Consequently 91% of the current Medicare Oxygen Providers will adjust their business model and/or will likely go out of business under the current competitive bidding plan. This is a direct result of the fact that oxygen is a primary source of revenue for most DME Providers. Obviously this will do away with hundreds and thousands of jobs throughout the country. In Charlotte, with one product category out of 10, that is likely to equal up to 1200 jobs. You can multiply that by 10 product categories and the 10 MSA's – just in the FIRST ROUND alone!

In this first round, CMS announced that an estimated 130 oxygen providers in and around Charlotte would be reduced to 11. CMS's selection of a relatively small number of suppliers would have resulted in a tremendous and unrealistic increase in the ratio of beneficiaries to supplier. Another way to look at this is that less than 10% of the existing suppliers survived the bid. Ladies and Gentlemen, there is no way that these 11 providers can adequately satisfy the needs of the patients that 130 providers had been supplying in the Charlotte/Gastonia CBA. Specifically, CMS provided information that in 2006 the allowed oxygen concentrator services totaled 79,353 distributed by 130 suppliers or 610 per provider. The bid winning 11 suppliers will now be providing services for over 7,200. Will not happen!! Last week, we had a snow shower in Charlotte resulting in ice. This often shuts down the community. How can these 11 suppliers provide emergency service to all the patients affected by an ice storm in a six county area? I was personally delivering oxygen tanks during the days following Hurricane Hugo. We were without power for weeks.

To narrow down the results of the competitive bid program for my company; we have eliminated 7 positions; 4 full time positions and 3 part time positions. This is 30% of my staffing level. That is very painful as a business owner; many of these were long time friends and colleagues.

Full Service DME suppliers can traditionally provide all the DME needs of the patient. Items such as wheelchairs, hospital beds, oxygen, enteral nutrients, and walkers may be provided by as many as five (5) different suppliers under the proposed competitive bidding plan. How confusing will this be Medicare Beneficiary's, caregivers, and those who facilitate the discharge planning for patients leaving the hospital?

Ultimately, access will be an issue. We spoke of the service component but the remaining few suppliers will result in service access for many of our nations' seniors.

On a very personal note: Our company has been contacted on many occasions after hours or on weekends by Clinical Case Managers wanting to execute a discharge from the hospital. More times than I can tell you, the referral source tells us they contacted one of competitors and could not get anyone to return their phone call. They have told us they know they can always depend on us because of our Service Component. Under the proposed Competitive Bidding Scheme the small number of providers can only provide sub-standard service because they will be spread so thin. Patients will suffer and ultimately there will be a cost shift from paying DME providers to paying for extended hospital stays because the hospitals will not be able to discharge the patients due to the equipment not being delivered. Home DME saves the government money!!

During the period of time that we were notified that we were not invited to the first round of bidding through the day that the program officially started, March 24 – June 30th we were constantly working to notify our patients of the change. The information that CMS sent to the beneficiaries was very confusing and left a lot to the imagination. We sent letters to our Medicare Beneficiaries explaining to them of the need to change providers. We had patients and clients up in arms saying they did not want to change providers. They were making comments that they had purchased their supplies from Griffin for years.

Also, we had planned on moving our facility and expanding, but due to the loss of the Competitive Bidding Contract; we placed all those plans on "hold."

The reality is that we lost the bid but we truly were the Winner! I am totally convinced that the limited number of bid winners will be unable to fulfill their commitment of the contract. I feel very strongly that many of the bid winners will not be able to provide any level of quality care or service to the Medicare Beneficiary. The poor service will cost our health care system additional dollars, create additional hospital admissions, and ultimately cost the Medicare Program higher prices due to the lack of competition.

The DME Industry is highly regulated – Nationally by The Office of Inspector General, Medicare's Anti Fraud Unit & Benefit Integrity Unit, The Judicial System, National Supplier Clearinghouse, and in North Carolina, The NC Board of

Pharmacy, NC Department of Health & Human Services, The NC Respiratory Care Board, and various other entities. Additionally, CMS is requiring the DME Companies be accredited by an ISO 9001:2000 Certified Accrediting Companies.

Medicare has many choices to reduce costs within the entire program. The attached peer review, an independent study by Brett Katzman and Kerry Anne McGeary states the following: "*The competitive bidding process is examined on a theoretical level. It is shown that the CMS competitive bidding process (auction) is inefficient, leads to price increases, and may cause decreases in the quality of services.*" The Competitive Bidding Process is Bad Policy; bad for consumers, bad for suppliers, and provides no significant savings to the government. It is inefficient and will ultimately create higher prices. We ask that the Medicare Competitive Bidding implementation be eliminated. At the very least let's have an in-depth and detailed review, work with the industry insiders to seek alternatives that will preserve the program integrity, maintain beneficiary freedom of choice in the selection of their provider and ultimately maintain a competitive marketplace that will drive value added services with competitive pricing.

I am very grateful for the opportunity to speak to you and just like I shared with President Obama in a recent letter, I welcome the opportunity to assist in seeking solutions.

Thank you!

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Will Competitive Bidding Decrease Medicare Prices?

Brett Katzman* and Kerry Anne McGeary†

Recent measures to reduce Medicare spending include the use of competitive bidding in determining reimbursement prices. Several competitive bidding experiments have been conducted by the Centers for Medicare and Medicaid Services (CMS) to determine reimbursement prices. This paper investigates the use of competitive bidding to set reimbursement prices for durable medical equipment, prosthetics, orthotics, and supplies. First, the competitive bidding process is examined on a theoretical level. It is shown that the CMS competitive bidding process (auction) is inefficient, leads to price increases, and may cause decreases in the quality of services. Next, data supporting the theoretical predictions are presented. Finally, we suggest that a descending variant of the Ausubel, Cramton, and Milgrom (2006) clock-proxy auction be used.

JEL Classification: I11, I18, H51, D44

1. Introduction

The Balanced Budget Act of 1997 granted the Centers for Medicare and Medicaid Services (CMS) congressional approval to implement up to three demonstration projects to investigate competitive bidding as a means of choosing Medicare providers. Officially deemed Durable Medical Equipment and Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Demonstration Projects, three experiments have been completed. Two projects were conducted in the Polk County, Florida, area (Polk County Round I and Polk County Round II), and another was implemented in the San Antonio, Texas, area (San Antonio).

Experimentation with DMEPOS, in which area Medicare expenditures currently total over $6 billion, is based on CMS's expectation of significant savings relative to the past procedure for setting reimbursement prices. This expectation of savings is no more evident than in the following excerpt from the Request for Bids sent to potential Polk County suppliers in January of 1999. It stated, "Medicare payments for DMEPOS are based on outdated fee

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schedules required by law. Studies by the General Accounting Office (GAO) and the Office of the Inspector General have found that payments allowed currently by Medicare fee schedules often include unreasonably high markups. These studies show that Medicare payments for certain DMEPOS items are greater than payments made by other insurers and sometimes greater than prices charged at retail outlets for customers who are not Medicare beneficiaries."

The decision to use competitive bidding as an alternative to outdated, inflated fee schedules was based on two appealing properties of competitive bidding. First, competitive bidding is commonly lauded for the competition it promotes, and CMS expected lower reimbursement prices to result from increased competition.[1] Second, the competitive bidding procedure gives CMS a hand in determining firm eligibility, thus ensuring quality service for Medicare recipients and protecting against collusion. The premise of our paper is that while utilizing competitive bidding in the Medicare process is an excellent idea, the format with which CMS experimented hinders both CMS and its beneficiaries from achieving greater savings.

The CMS bidding process consists of three stages. A pre-screening stage determines each firm's ability to supply quality service to Medicare beneficiaries within different categories of goods (e.g., surgical supplies, oxygen equipment). In stage 2, eligible firms submit bids on each and every individual good within the categories on which they are bidding, and winners are determined. Finally, the price of an individual good is determined using a weighted average of the winners' bids on that good.[2]

While the pre-screening stage appropriately identifies quality Medicare providers, the rules for determining winners and setting prices are complex. Both processes involve an aggregation of bids on individual goods within a given product category. The process for determining winners requires the calculation of a "composite bid" (weighted average)[3] for each firm based on its individual bids on the different goods within a category. Those firms with the lowest composite bids win the bidding process and are deemed official Medicare providers. The price that official Medicare providers are allowed to charge for individual *units* of a *good* is then a weighted average of the winning bids on that *good*.[4]

In designing the competitive bidding experiment, CMS envisioned a process in which the individual bids submitted by firms would represent the lowest price at which they were willing to supply each good. Unfortunately, our theoretical models show that equilibrium bidding is conflated by the aggregation rules and that truthful bidding of costs is not elicited by the CMS rules. This, in turn, implies that there are circumstances in which the CMS mechanism will fail to select the lowest cost providers.

The root of the problem is that a firm's composite bid, and not its individual component bids, determines whether or not the firm is given Medicare provider status. Thus, while the individual bids are used to calculate Medicare prices, the composite bid determines whether or not the firm becomes a Medicare provider. As the composite bid is a linear function of individual bids, this avails the firm of a number of ways of achieving a targeted composite bid

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[1] Of course, lower prices do not guarantee lower expenditures if demand is elastic. However, it is commonly noted that demand for medical supplies tends to be inelastic.

[2] Unlike many auctions, the CMS DMEPOS auction does not generate revenue. The bidding process is intended to determine which firms can supply the goods at the lowest cost and set the prices of the goods accordingly

[3] Weights on individual bids are determined by CMS prior to bidding and represent anticipated demand for the good relative to the anticipated demand for the product category as a whole.

[4] We are careful to maintain the term *good* to designate tangibly different products, while the term *unit* is used to keep track of quantities of a specific *good*.

regardless of the cost of supplying individual goods. At best, this leads to vast uncertainty regarding prices on individual goods. At worst, it opens the door for "gaming" of the system.

Instances of gaming linear composite-type bidding systems have been documented for auctions of U.S. timber (see Baldwin, Marshall, and Richard 1997; Athey and Levin 2001) and California electricity (see Bushnell and Oren 1994; Gribik 1995). The basic idea extends to the CMS rules, and our models below show that "gaming" is in fact optimal behavior for firms. Specifically, if a firm believes that CMS has underestimated relative demand for a good, it can increase its bid on that good while lowering its bid on a good for which it believes relative demand forecasts are too high, all while simultaneously maintaining its targeted composite bid. In doing so, it will be able to increase the price of the good that it believes will have relatively high demand by simply lowering its bid on the good for which it forecasts relatively low demand. This is clearly a profitable strategy that has adverse pricing repercussions.

The main prediction from our model is that while the CMS format will achieve price reductions on some goods, this will most likely occur at the expense of increased prices on other goods. Using data from completed demonstration projects, we establish preliminary evidence that this is the case, adding fuel to the growing literature on the inefficient pricing structure within the Medicare program (see Dor, Held, and Pauly 1992; Cutler 1995; Dor and Watson 1995; Dor 2004). We find that price increases occur often and that the gains from competitive bidding (in its current form) may not be as large as CMS had hoped. The fact that when a firm bids high on one good it must correspondingly bid low on another good in order to reach its targeted composite bid introduces additional, less quantifiable ramifications as well. Specifically, if the price of a good is bid too low, firms may tacitly avoid supplying it, thereby increasing consumer search costs and decreasing quality of service.[5]

Finally, it is our contention that the shortcomings of the CMS design relate to a fundamental misunderstanding of auctions. A common misconception is that the desirable properties of single-unit auctions extend to multi-unit auctions (see Ausubel and Cramton 2002, p. 1, for a discussion). However, recent theoretical breakthroughs show that there are actually very few multi-unit auctions that possess the famous efficiency and revenue-generating properties of single-unit auctions. In fact, the majority of multi-unit auctions are inefficient and can deliver vastly different expected outcomes (see Engelbrecht-Wiggans and Kahn 1995; Noussair 1995; Katzman 1999; Ausubel and Cramton 2002). Even the famed Vickrey (1961, 1962) auction, lauded for eliciting bids equal to costs/values, is susceptible to collusion and third-party manipulation (see Graham and Marshall 1987; Rothkopf, Teisberg, and Kahn 1990). Fortunately, recent developments in auction design by Ausubel (2004), Reny and Perry (2005), Ausubel and Milgrom (2006), and Ausubel, Cramton, and Milgrom (2006) have addressed the shortcomings of existing auction formats and provide a wealth of realistic alternatives. In the end, we encourage CMS to investigate the merits of these new bidding processes.

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[5] Outright denial of service would certainly have negative future impacts on a firm dealing with CMS. However, other methods, such as keeping the customer on hold indefinitely, may be as effective and less easily identified. In addition, poor service to a customer on the first transaction (perhaps in terms of late delivery) may encourage the customer to seek out other, less convenient suppliers. While it may take years to analyze the impact of the auctions on service quality, in a baseline study, Hoerger, Finkelstein, and Bernard (2001) found that prior to the inception of the demonstration project, Medicare beneficiaries were highly satisfied with their Medicare providers, thus providing a benchmark to which post-auction surveys can be compared. This topic is discussed in greater detail in section 5

Table 1. Product Categories by Project (Values Indicate No. of Items)

Category	Polk County Round I	San Antonio	Polk County Round II
Hospital beds and accessories	31	18	13
Oxygen equipment and supplies	15	10	8
Enterals	25		
Urologicals	40		22
Surgical dressing and supplies	52		28
Manual wheelchairs and accessories		60	
Non-customized orthotic devices		46	
Nebulizer inhalation drugs		27	

2. The CMS Bidding Process

The competitive bidding projects were run in Polk County, Florida, and San Antonio, Texas. The product categories targeted by CMS for the Polk County Round I, San Antonio, and Polk County Round II projects appear in the first column of Table 1. The choice of these categories was based on the anticipation of significant savings on these types of equipment. Any firm wishing to provide goods in the categories listed in Table 1 to Medicare beneficiaries in Polk County or San Antonio during the project was required to participate in the process. That is, firms not submitting bids or firms who were unsuccessful at the auction could *not* supply any good in the categories listed in Table 1 to Medicare beneficiaries in the respective regions.[6]

At the inception of a project, a Request for Bids (RFB) was sent out to potential suppliers. The RFB detailed the process that firms had to follow to be eligible for consideration; it also explained the overall process. In addition, past demand data were provided to aid firms in estimating demand in subsequent years. Included in these data were the turnover of beneficiary users for each good within each product category, the total number of beneficiary users for all goods in each product category, the number of new beneficiary users for each good in a product category, and trends in beneficiary usage.

The initial stage of each project focused on eligibility. CMS's goal was to choose firms that would provide reliable, quality service to Medicare beneficiaries. At a minimum, firms had to comply with all state and federal regulatory requirements, all Medicare and Medicaid statutes and regulations, all billing guidelines pertaining to Medicare, and all National Supplier Clearinghouse standards. If a firm met all of these criteria, it was invited to submit bids.[7]

Bidding by eligible firms was done by category. Firms that submitted bids in a given product category were directed to submit a bid on *every* individual good in that category. That is, a firm that bid on one good in a category had to bid on all goods in that category. Once bids were received, they were reviewed, and a 10-day grace period was given, during which the firms were allowed to amend or revise their bids. After that, all bids were final.

[6] The numerical entries in Table 1 denote the number of unique goods that were included in each category. The reader may be interested in noting that each category included both complement goods (e.g., hospital beds, hospital bed rails) as well as substitute goods (e.g., composite dressing without adhesive, composite dressing with adhesive).

[7] In fairness to smaller suppliers, those deemed eligible were allowed to form networks. To avoid anti-competitive behavior, a network's total market share could not exceed 25% of the Medicare market for any product category. Members of networks were not allowed to submit individual bids in addition to the network's bids.

CMS indicated that bids should represent the price below which the firm would not be able to supply that good.[8]

Before going into the details of the bidding process, it will be helpful to point out a few important traits of this design. First, the process did not generate revenue; it allocated the right to be a Medicare provider, and bids were only used to select Medicare providers and to calculate the allowable reimbursement prices. Second, since CMS's goal was to reduce Medicare prices, it was looking to identify those producers that submitted the lowest bids. Finally, and most importantly, this process was multi-unit in nature, thereby limiting the applicability of a vast majority of the auction literature.

Upon receipt of all bids, a process was set in motion for determining winners and for subsequently setting prices. First, a firm's bids on individual goods in a category were used to form a "composite bid" for the firm in that category.[9] Calculation of the composite bid used CMS-specified weighting coefficients (that represented the anticipated demand for individual goods relative to demand in the category as a whole) and the firm's individual bids.

Consider a category with I distinct goods. Denote the weight assigned to good i by w_i. If $\hat{v}_i$ is the estimated volume for good i and $\hat{V}$ is the estimated volume for the entire product category, then w_i is calculated as $w_i = \hat{v}_i/\hat{V}$, which implies $\Sigma^I_{i=1} w_i = 1$. Inherently, CMS used estimated volume as a forecast of demand in the subsequent year.[10] The resulting weights were given to the firms as part of the RFB and were therefore known to the firms prior to bid submission.

CMS next calculated weighted bids ($\tilde{b}_{in}$), using each firm's (n) individual bids (b_{in}), as $\tilde{b}_{in} = w_i b_{in}$. Finally, the firm's composite bid, B_n, was calculated as $B_n = \Sigma^I_i \tilde{b}_{in}$. After they had been calculated, the composite bids were placed in ascending order. Using demand information for each good, CMS determined how many firms would be necessary to meet demand in each category. Denote this number of firms by M. The Mth lowest composite bid was deemed the cutoff composite bid, $\tilde{B}$, in that category, and the firms submitting the M lowest bids became Medicare providers of goods in that category. CMS refers to bids at or below the cutoff composite bid as being in the "competitive range."

The final step in the process was determining the prices at which providers would be reimbursed. First, a ratio representing the competitiveness of each firm's composite bid was calculated. Indexing firms by $m = 1,\ldots, M$, the ratio (r_m) is $r_m = \tilde{B}/B_m \geq 1$. Next, an adjusted bid price (a_{im}) was calculated for each good (i) using the firm's competitiveness ratio and its original bid for that good, such that $a_{im} = b_{im} \times r_m$. The demonstration price that was set on each good was the average of the winning firms' adjusted bid prices, or $p_i = \Sigma^M_{m=1} a_{im}/M$.

Finally, the amount reimbursed by Medicare to the winning firms was equal to 80% of the demonstration price, p_i, and the beneficiary co-payment was 20%. The demonstration prices, Medicare reimbursement, beneficiary's co-payment, and pre-experiment prices for each project were listed on the CMS DMEPOS Projects website, available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp (CMS 2006). These data are analyzed in section 5.

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[8] A seemingly minor but related rule turns out to be very important in our empirical analysis. As bids were expected to represent the cost of supplying the good, bids below wholesale prices were not allowed. Unfortunately for our empirical analysis, CMS gave no specifics as to what these wholesale prices were, and internet searches of wholesale prices at the time produced a wide variety of possibilities.

[9] CMS refers to the composite bid as a composite bid price. However, we will refer to it as the composite bid so that we may reserve the word price for that amount paid for one *unit* of a *good* by the beneficiary.

[10] This is consistent with how CMS calculated the weights for the San Antonio and Polk County Round II projects. In the Polk County Round I project, the weights were the estimated claims for an item divided by the total estimated claims for the total category

3. Full Information

The model presented in this section is intended to convey our basic results to a general audience. The model is one of full information with respect to bidder costs. That is, every firm knows every other firm's marginal cost structure.[11] We do allow for differences between firm estimates of volume and CMS estimates. Despite the difference in firm and CMS estimates, one can still think of this as a game with full information by assuming that the CMS weights were credibly fixed in the RFB before additional information allowed firms to obtain better estimates. Consider a case in which N firms compete to be suppliers of two different goods (goods 1 and 2) within the same product category. CMS has determined that two of the N firms will be chosen to supply the two goods. Each firm (n) is assumed to have the ability to supply half of the total volume of good i ($v_i/2$) at a constant marginal cost of c_{in}.[12] CMS has demand estimates of $\hat{v}_{1,CMS}$ and $\hat{v}_{2,CMS}$ that give a total volume estimate of $\hat{V}_{CMS} = \hat{v}_{1,CMS} + \hat{v}_{2,CMS}$ and weights $w_1 = \hat{v}_{1,CMS}/\hat{V}_{CMS}$ and $w_2 = \hat{v}_{2,CMS}/\hat{V}_{CMS}$. Firms have their own demand estimates, $\hat{v}_{1,firm}$ and $\hat{v}_{2,firm}$, that result in a total volume estimate of $\hat{V}_{firm} + \hat{v}_{1,firm} + \hat{v}_{2,firm}$ and weights $\gamma_1 = \hat{v}_{1,firm}/\hat{V}_{firm}$ and $\gamma_2 = \hat{v}_{2,firm}/\hat{V}_{firm}$. In order to limit complexity, we assume that each firm has the same estimates of relative demand, γ_1 and γ_2.

Strategies for firm n (=1,..., N) are bids b_{1n} and b_{2n}. These bids are aggregated using the weights w_{1n} and w_{2n} to form firm n's composite bid, $B_n = w_1 b_{1n} + w_2 b_{2n}$. From this it is easily seen that equilibrium bidding is governed by two factors. First, whether a firm wins or loses is solely determined by its composite bid, and, hence, we must identify the equilibrium composite bid (B^*_n) for each firm. Second, the individual components (b^*_{1n} and b^*_{2n}) of the equilibrium composite bids that maximize the payoff of each firm must be identified.

Generally, Nash equilibrium in an auction requires that no firm wishes to change its bids, given the bids placed by the other firms. Here, this reduces to specifying that winning firms do not wish to raise their bids and that losing firms could not lower their bids in order to become a profitable winner.[13] The firms submitting the two lowest composite bids "win" the process, and the individual bids placed by the winning firms are then used to calculate the prices in each market. We make the simplifying assumption that the price of a good is simply the average of the winning bids on that good.[14]

In deriving equilibrium bids, it will be useful to rank firms based on their costs of providing a "composite" good that consists of the individual goods supplied by winning firms. Specifically, the cost of providing this composite good is $(\hat{v}_{1,firm}/2)c_{1n} + (\hat{v}_{2,firm}/2)c_{2n} = (\gamma_1 c_{1n} + \gamma_2 c_{2n})(\hat{V}_{firm}/2)$. Denote (parenthetically) the firm with the lowest cost of providing the composite good as firm (1), the firm with the second lowest costs of providing the composite good as firm (2), and so on. More generally, let $MC_{(n)}$ represent firm n's cost of providing the

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[11] The reader is referred to Hirshleifer and Riley (1992, chapter 10) for background on auction games with full information

[12] While this assumption is simplistic, our results indicate that the pitfalls in the CMS design would only be exacerbated in a more complex environment.

[13] Clearly, a winning firm would not want to lower their bid as it would ONLY lower its profits since it was already winning.

[14] By eliminating the adjusted bid price from our model we are simplifying the trade-off faced by firms in choosing their optimal composite bid It should be noted that by lowering their composite bid, firms in a CMS auction can increase their competitiveness ratio, thereby affecting prices in the entire category However, this incentive still leads to bids that are skewed and not based on costs, and we use the simplified rule for ease of exposition.

composite good, let $b_{i(n)}$ represent firm (n)'s individual bid on good i, and let $B_{(n)}$ represent firm (n)'s composite bid.

In order to isolate the equilibrium composite bids, we first point out that a winning firm expects to earn $[\gamma_1(p_1 - c_{1n}) + \gamma_2(p_2 - c_{2n})](\hat{V}_{firm}/2)$, where p_i is the average of the winning bids on good i. It will be instructive to write these profits as $[(\gamma_1 p_1 + \gamma_2 p_2) - (\gamma_1 c_{1n} + \gamma_2 c_{2n})](\hat{V}_{firm}/2)$ $= [(\gamma_1 p_1 + \gamma_2 p_2) - MC_n](\hat{V}_{firm}/2)$. Clearly, a firm will not submit individual bids that result in equilibrium prices that give lower revenue than the firm's costs, MC. From this point of view, the CMS process is similar to a Bertrand pricing game in which firms' marginal costs are given by $MC_{(1)}$, $MC_{(2)}$,..., $MC_{(n)}$. Not surprisingly, equilibrium here requires a condition similar to that in the Bertrand game in that equilibrium bids must gravitate to a level at which revenues for the two most competitive firms would let the third most competitive firm break even, which is equivalent to the following condition

$$\frac{\hat{V}_{firm}}{2}\left[\gamma_1 \frac{b_{1(1)} + b_{2(2)}}{2} + \gamma_2 \frac{b_{2(1)} + b_{2(2)}}{2}\right] = MC_{(3)}. \tag{1}$$

At the same time, all other firms must bid aggressively above their MC using a mixing distribution, such that the marginal payoff of firms (1) and (2) from increasing one of their individual bids is outweighed by the chance that firm (3) would displace them as a winner.[15]

Like the Bertrand game, Equation 1 combined with other firms mixing aggressively above their MC is necessary for Nash equilibrium. However, unlike the Bertrand game, Equation 1 is not sufficient for Nash equilibrium here. The lack of sufficiency occurs because there are many combinations of individual bids by firms (1) and (2) that satisfy Equation 1, indicating that it is also necessary that firms choose their individual bids (b_{1n} and b_{2n}) optimally. The relation between Equation 1 and the optimality of the individual bids is best expressed by the following linear programming problem:

$$\begin{aligned} &\min_{b_{1n}, b_{2n}} \quad w_1 b_{1n} + w_2 b_{2n} \\ &s.t. \quad \frac{\hat{V}_{firm}}{2}\left[\gamma_1 \frac{b_{1(1)} + b_{2(2)}}{2} + \gamma_2 \frac{b_{2(1)} + b_{2(2)}}{2}\right] = MC_{(3)}. \end{aligned} \tag{2}$$

The Nash equilibrium caveat is that firms (1) and (2) must solve this problem simultaneously while the other firms mix aggressively above their MC.

The fact that the equilibrium conditions can be expressed as a linear programming problem with one constraint indicates that there are three possible outcomes. First, if the firm's estimate of relative demand for good 1, γ_1, is less optimistic than the CMS estimate w_1 (inferring that the firm's relative demand estimate for good 2, γ_2, is more optimistic than the CMS estimate w_2), then there is a corner solution in which $b_{1(n)} = 0$ and $b_{2(n)}$ is chosen so as to satisfy Equation 1. Second, if the firm's estimate of relative demand for good 2, γ_2, is less optimistic than the CMS estimate w_2 (inferring that its relative demand estimate for good 1, γ_1, is more optimistic than the CMS estimate w_1), then there is a corner solution in which $b_{2(n)} = 0$ and $b_{1(n)}$ is chosen so as to satisfy Equation 1. Finally, in the case in which the firm's estimates agree with CMS estimates, the choices of $b_{1(n)}$ and $b_{2(n)}$ are not unique, and any combination that satisfies Equation 1 is optimal.

[15] As the purpose of this section is to provide a heuristic view of equilibrium and not a formal proof, we do not derive these mixing distributions here. However, we do note that they exist and lead to the equilibrium bids by winning bidders mentioned in this section. The interested reader is referred to Hirshleifer and Riley (1992, chapter 10) for a discussion of mixing strategies in full information auctions.

Table 2. Marginal Cost Structure for Example 1

	A	B	C	D
c_{1n}	\$1.00	\$1.00	\$2.50	\$1.50
c_{2n}	\$1.00	\$3.00	\$1.00	\$1.50
$MC_n = 2[(1/2)c_{1n} + (1/2)c_{2n}]$	\$2.00	\$4.00	\$3.50	\$3.00

Several conclusions can be drawn from the equilibrium discussed above. First, because of the corner solutions, prices will not represent the actual costs of providing the goods, which was one of CMS's goals. Further, the resulting prices will be skewed depending on which goods had relative demand that was over/underestimated. Finally, it is possible that equilibrium bids will result in low cost providers being shut out of the market and relatively inefficient firms becoming Medicare providers. The following numerical examples highlight each of these problems with the current format and are aimed at providing a better understanding of the relationship between the optimality of the individual bids and Equation 1.

Example 1

Let there be four firms ($n = A, B, C, D$) competing for two positions as Medicare suppliers. Assume that these firms have the constant marginal costs presented in Table 2 and that both CMS and the firms believe that $v_1 = v_2 = 2$, resulting in weights of $w_1 = w_2 = \gamma_1 = \gamma_2 = 1/2$. Based on Table 2, firm C is (3) and $MC_{(3)} = \$3.50$. Since the firms' estimates match CMS estimates, it follows that composite bids of \$1.75 by firms A and D will result in revenues equal to \$3.50, which satisfies Equation 1 regardless of the specific individual bids placed by those two firms. Without regard to how firms A and D choose their individual bids, the outcome of the bidding process is inefficient, since firm D is not one of the two most efficient providers of either good, yet firm D wins. This inefficiency is most easily seen by comparing the outcome to that which would result if the prices of each good were determined under Bertrand competition. In that case, good 1 would be provided by firms A and B for a price of \$1.50 and good 2 would be provided by firms A and C for a price of \$1.50. Therefore, simply opening the market to pricing competition would not only lead to a situation in which the most efficient firms provide the goods, but it would also result in an overall reduction in expenditures of \$0.50 (\$3.00 vs. \$3.50).[16]

Since the firms' estimates match CMS's estimates in this example, any combinations of individual bids by firms (1) and (2) that lead to composite bids of \$1.75 are optimal. Thus, there is substantial variability in the expectation of prices, and very few of the possible outcomes will mirror prices being set according to the cost of providing the goods. While the variability of prices is not of consequence to the firms (since equilibrium requires that all combinations result in the same cost of providing the composite good), price variability will lead to transfers of consumer surplus such that one group of consumers subsidizes another. The next example shows that this type of subsidization is virtually guaranteed if CMS estimates do not match the firms' estimates.

[16] One could argue that the inefficiencies and price increases might be beneficial if the government could reduce transaction costs by limiting the number of suppliers and bundling the contracts. However, our communications with CMS indicated that price reductions were the primary objective and that significant savings in transactions costs were not expected.

Table 3. Marginal Cost Structure for Example 2

	A	B	C	D
c_{1n}	\$1.00	\$1.00	\$2.50	\$1.50
c_{2n}	\$1.00	\$3.00	\$1.00	\$1.50
$MC_n = 3[(2/3)c_{1n} + (1/3)c_{2n}]$	\$3.00	\$5.00	\$6.00	\$4.50

Example 2

Let the four firms from Example 1 have estimates of relative demand (γ_1 and γ_2) that differ from CMS's estimates. Rather than believing that there will be two units of each good demanded, the firms correctly believe that there will be four units of good 1 and two units of good 2 demanded, giving $\gamma_1 = 2/3$ and $\gamma_2 = 1/3$. Given its estimates (from Example 1) of $w_1 = w_2 = 1/2$, CMS will still be selecting two firms to supply the goods, and, for simplicity, we assume that each of the two winning firms will supply two units of good 1 and one unit of good 2 (i.e., the CMS estimates are incorrect). All other information is known to the firms, including the constant marginal costs given in Table 3. The firms' marginal costs of supplying the "composite good" (two units of good 1 and one unit of good 2) are therefore \$3.00, \$5.00, \$6.00, and \$4.50, respectively.

Equation 1 requires that firms A and D choose individual bids that result in prices such that if they win, the revenue from supplying the composite good is \$5.00 [$= MC_{(3)}$]. In order to investigate the importance of choosing the individual bids optimally, assume for the moment that firms A and D ignore the corner solution and bid $b_{1A} = b_{1D} = \$1.00$ and $b_{2A} = b_{2D} = \$3.00$ (which, incidentally, are firm B's marginal costs). These bids result in composite bids of \$2.50, which, if they win, yield prices $p_1 = \$1.00$ and $p_2 = \$3.00$ and a cost of supplying the composite good of 2(\$1.00) + 1(\$3.00) = \$5.00, thus satisfying Equation 1. However, since these individual bids were not chosen optimally, they will not result in firms A and D winning. To see this, consider the result if firms B and C bid $b_{1B} = b_{1C} = \$4.00$ and $b_{2B} = b_{2C} = \$0.00$. These bids would result in composite bids of 1/2(\$4.00) + 1/2(\$0.00) = \$2.00, which would defeat the composite bids of \$2.50 made by firms A and D. At the same time, the resulting prices $p_1 = \$4.00$ and $p_2 = \$0.00$ result in revenues from supplying the composite good of \$8.00, which is profitable for both firms B and C, since their costs of supplying the composite good are \$5.00 and \$6.00, respectively. In other words, despite the fact that their bids satisfied Equation 1, by not choosing their individual bids optimally, firms A and D opened the door for firms B and C to game the system and win the process.

To see that adhering to the corner solution shuts firms B and C out of the market, consider the result when firms A and D optimally bid $b_{1A} = b_{1D} = \$2.50$ and $b_{2A} = b_{2D} = \$0.00$. By submitting these bids, firms A and B generate composite bids of 1/2(\$2.50) + 1/2(\$0.00) = \$1.25 and sets prices $p_1 = \$2.50$ and $p_2 = \$0.00$. At these prices, firm B would make zero profit even if it won, and firm C would lose money. Hence, neither firm B nor firm C can profitably submit a lower composite bid (as doing so would earn them negative profits), and the equilibrium consists of highly skewed prices.

Finally, consider what happens when firms A and D follow the strategy prescribed by CMS of bidding their costs. In this case, such a strategy results in bids $b_{1A} = \$1.00$, $b_{1D} = \$1.50$, $b_{2A} = \$1.00$, $b_{2D} = \$1.50$. The resulting composite bids are $B_A = \$1.00$ and $B_D = \$1.50$, yielding prices $p_1 = \$1.25$ and $p_2 = \$1.25$, which generate revenue of supplying the composite good of \$3.75. While this shuts firms B and C out of the market and is profitable for firms A

and D, it is clear from the above explanation that this result is suboptimal, since the corner solution bids, $b_{1A} = b_{1D} = \$2.50$ and $b_{2A} = b_{2D} = \$0.00$, generated revenues of \$5.00. The reason that bidding one's costs is not an equilibrium strategy is that it does not satisfy Equation 1 with equality and thus leaves money on the table.

The fact that demand in this model is perfectly inelastic implies that skewed prices simply transfer consumer surplus and may not be alarming from certain policy perspectives. However, since different consumers may be buying the different goods, we anticipate that high price increases on some goods will lead to protests by consumers of those goods. All in all, the CMS bidding process clearly does not elicit the intended truthful bidding of costs and can lead to strategic skewing of bids if firm estimates of demand are not aligned with the CMS estimates. The next section extends these instructive examples and shows that they are robust in a world of incomplete information.

4. Incomplete Information

We now show that the predictions from the previous section are valid in an incomplete information environment. In this model, there are N risk-neutral firms competing for the right to supply a product category containing i (=1, 2) distinct goods. Firm n (=1,..., N) has constant marginal cost c_{in} of providing good i. CMS has determined that M suppliers are necessary to provide the entire product category. As in the previous section, we impose a simplified version of the rule for calculating reimbursement prices on each good. Once again, it is the average of the winning individual bids on that good.

Each firm submits bids b_{1n} and b_{2n}, and their composite bids ($B_n = w_1 b_{1n} + w_2 b_{2n}$) are calculated using the CMS weights (w_1 and w_2). In formulating a firm's expected payoff function, we once again allow for the possibility that firm n has its own (exogenous) forecasts of the relative demands (γ_{1n} and γ_{2n}). Since firms are assumed to be risk neutral, γ_{in} will enter the profit function linearly and can be viewed as either the true value of demand or an expectation.

It follows that firm n's objective function can be written as

$$\int_{B_n}^{B_U} [\gamma_{1n}(p_1(b_{1n},x) - c_1) + \gamma_{2n}(p_2(b_{2n},x) - c_2)] f(x)\,dx, \tag{3}$$

where the integral is taken over events in which firm n wins, where $f(x)$ is the (continuous) density function of the Mth lowest of the firm's opponents' composite bids,[17] where B_U is the highest composite bid that any firm will place, and where $p_i(b_{in},x) = \Sigma^M_{j=1} E(b_{ij}|x)/M$. The firm's trade-offs in this problem are twofold. First, the firm must target a specific composite bid that weighs the fact that a lower composite bid is more likely to win with the fact that placing a lower composite bid requires lowering the individual bid on a good, thus lowering the profit margin on that good if the firm wins. On the other hand, while increasing an individual bid will increase profitability on that good, it also increases the composite bid, making it less likely that the firm will win.

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[17] We focus on the Mth lowest of the opponents' composite bids because if the optimizer submits a lower composite bid, it will be a winner.

Maximizing Equation 3 with respect to b_{1n} and b_{2n} yields the following first-order conditions:

$$\frac{\gamma_{1n}}{M}[1 - F(B_n)] - w_1[\gamma_{1n}(p_1[b_{1n},B_n] - c_{1n}) + \gamma_{2n}(p_2[b_{2n},B_n] - c_{2n})]f(B_n) = 0,$$

$$\frac{\gamma_{2n}}{M}[1 - F(B_n)] - w_2[\gamma_{1n}(p_1[b_{1n},B_n] - c_{1n}) + \gamma_{2n}(p_2[b_{2n},B_n] - c_{2n})]f(B_n) = 0$$

where $F(x)$ is the distribution function corresponding to $f(x)$. Taking the ratio of first-order equations gives the simple relation

$$\frac{\gamma_{1n}}{\gamma_{2n}} = \frac{w_1}{w_2}. \tag{4}$$

Equation 4 provides several enlightening characteristics of equilibrium bidding. First, if a firm's demand estimates are in agreement with the CMS estimates, any combination of individual bids that leads to the firm's optimal composite bid is equally good, as in Example 1. Alternatively, if a firm's estimates do not align with CMS's estimates, Equation 4 cannot hold, and there is no interior solution. The theoretical result is that the bid on the good for which CMS estimates of relative demand are too optimistic would be zero, while the entirety of the composite bid would be placed on the good for which CMS estimates are overly pessimistic, as in Example 2.

The intuition behind this last fact is simple. If $\gamma_{1n} < w_1$, then the firm expects lower relative demand on good 1 than the CMS estimates indicate. Thus, the importance of the individual bid on good 1 is being overstated. Hence, by lowering its bid on good 1, the firm can increase its bid on good 2, all the while maintaining the optimal composite bid. While this means that it will be accepting a lower price for good 1, it expects that the reduction in profits will be more than offset by the increase in profits caused by the increase in the price of good 2. Notice that a firm is even willing to take a loss on good 1, as it expects to be more than compensated by the additional profits generated on good 2. Practically, bids in the CMS process would not be lowered to zero because of the CMS rule that bids can not be below the wholesale price of the good.[8] Thus, the relevant corner solution here calls for bids equal to wholesale prices on the goods for which CMS overestimated relative demand.

5. Data

The preceding models have not only shown that the current rules of the CMS bidding process are suboptimal, they also provide us with predictions about bidding behavior and the resulting prices under these rules. It is these testable predictions that are the focus of this section. Before turning to the data, we offer a few comments concerning the limitations placed on empirical testing by the aggregation rules.

In our opinion, the most appropriate test of our theoretical predictions would involve the structural estimation of the stochastic properties of a firm's costs and how they relate to bids. However, we have seen that in equilibrium, the individual components of the composite bid may not matter, and even if they do, they depend on both the firm's costs and its forecasts of demand. It follows that there is no way to retrieve the individual marginal costs from individual bids. To compound this problem, CMS has not made the composite or individual bid information available. Hence, using structural econometrics to estimate the underlying

distribution of costs is not possible. Yet there is a wealth of information available on the CMS Website that can be utilized.[18] While the site is intended to provide suppliers and beneficiaries who are involved in the projects with information, it also provides us with a minimum amount of data that can be used to test our theoretical predictions. Specifically, the Website includes data from all three of the completed DMEPOS Competitive Bidding Demonstration Projects, including detailed demand information on each location for one year prior to the bidding stage of the project, a list of winning suppliers, and the old and new fee schedules.

The Polk County Round I data tell us that CMS received 73 composite bids from 30 different firms for the five product categories included in the project. These categories are as follows: enteral nutrition equipment (enterals), urological supplies (urologicals), surgical dressings, hospital beds and accessories (hospital beds), and oxygen supplies (oxygen). The top portion of Table 4A shows that 15 of the 30 bidding firms won the right to supply and how they were distributed across the categories. Anywhere from four to 13 firms were chosen as providers for product categories. Surgical dressings and urologicals have the smallest number of suppliers, four and five, respectively, while hospital beds and oxygen have the greatest number of suppliers with 10 and 13, respectively.

The lower portion of Table 4A describes the supplier situation for Polk County Round II.[19] This project had 17 independent firms win the bidding process. Of these 17 firms, eight were suppliers of hospital beds, 10 supplied oxygen, only four supplied surgical dressings, and six supplied urologicals. Only one of the 17 suppliers had responsibility for all categories, eight were suppliers of two categories, and another seven supplied only one category. Additionally, any firm responsible for surgical dressings supplied at least one other category.

The winning firms and the categories that they supply for the San Antonio project are listed in Table 4B. The San Antonio project received 179 composite bids from 70 different firms for the five product categories included in the project. These categories are as follows: hospital beds and accessories (hospital beds), nebulizer inhalant drugs (nebulizer drugs), non-customized orthotics (orthotics), oxygen supplies (oxygen), and manual wheelchairs (wheelchairs). Of the 70 firms, 51 won the right to be Medicare DMEPOS suppliers in San Antonio. Anywhere from 10 to 29 firms were chosen as Medicare providers for the various product categories. Orthotics and nebulizer drugs have the smallest number of suppliers, 10 and 11, respectively, while hospital beds and oxygen have the greatest number of suppliers, with 24 and 29 suppliers, respectively.

In order to investigate the impact of the bidding process on prices in each project, we begin by comparing the prices that resulted from the bidding process to the prices specified by the fee schedule prior to the project. Tables 5–8 show the results of our analysis. In Polk County Round I the average price decrease for all goods across all categories is remarkably small, 4.46%, compared to the expectation of significant savings.[20] Table 6 shows that the San Antonio project experienced a much higher average price decrease of 15.37%, while Polk County Round II showed improvement compared to Polk County Round I, with an average price decrease of 8.57%. Finally, over all of the projects the average price change, as illustrated

[18] As of December 2006, the Website is http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list asp

[19] Recall that Polk County Round II did not include the enterals category

[20] Hoerger, Finkelstein, and Bernard (2001) report a much better result (a 17% average price decline) for the Polk County Round I project. Unfortunately, this level of savings is misleading in that it only uses goods on which the prices actually fell in the calculation, thereby avoiding the basic tenant of our paper that the price decreases on some goods were only made possible by increases in the prices of other goods.

Table 4A. Demonstration Suppliers by Product Category, Polk County Round I (PCI) and Round II (PCII)

Polk County Round I					
Company	Enterals	Urologicals	Surgical Dressing	Hospital Beds	Oxygen Supplies
PCI-A	X			X	X
PCI-B	X	X	X	X	X
PCI-C					X
PCI-D	X			X	X
PCI-E	X			X	X
PCI-F	X			X	X
PCI-G					X
PCI-H				X	X
PCI-I		X	X		X
PCI-J			X		
PCI-K	X	X		X	X
PCI-L	X	X	X		
PCI-M				X	X
PCI-N		X		X	X
PCI-O				X	X
Total = 15	7	5	4	10	13
Polk County Round II					
Company	Enterals	Urologicals	Surgical Dressing	Hospital Beds	Oxygen Supplies
PCII-A	—			X	
PCII-B	—			X	X
PCII-C	—			X	X
PCII-D	—				X
PCII-E	—	X			
PCII-F	—	X			
PCII-G	—			X	X
PCII-H	—	X	X		
PCII-I	—	X	X		
PCII-J	—				X
PCII-K	—			X	X
PCII-L	—	X	X	X	X
PCII-M	—	X	X		
PCII-N	—			X	
PCII-O	—				X
PCII-P	—				X
PCII-Q	—			X	X
Total = 17		6	4	8	10

by Table 8, was a decline of only 9.22%, which most likely did not meet CMS's expectations of *significant* price reductions, since all of these calculations are relative to the outdated, inflated fee schedule.

Another result of interest is that the variation in the percentage change in price is quite large, with maximum price decreases of 70.07% for Polk County Round I, 34.69% for San Antonio, and 38.45% for Polk County Round II, compared to minimum price decreases (in other words, maximum price increases) of −458.65% for Polk County Round I, −100.00% for San Antonio, and −162.17% for Polk County Round II. Of the 162 goods involved in the Polk County Round I project, 50 actually experienced price increases, while 11 of the 162 goods in

Table 4B. Demonstration Suppliers for San Antonio (SA)

	San Antonio				
Company	Hospital Beds	Nebulizer Inhalation Drugs	Orthotics	Oxygen	Manual Wheelchairs
SA-A	X			X	
SA-B	X				
SA-C				X	
SA-D				X	
SA-E	X	X		X	X
SA-F				X	X
SA-G	X				
SA-H	X			X	X
SA-I		X		X	X
SA-J	X	X		X	X
SA-K		X		X	
SA-L	X				X
SA-M				X	
SA-N		X			
SA-O	X			X	X
SA-P	X				X
SA-Q			X		
SA-R				X	
SA-S				X	
SA-T		X			
SA-U			X	X	
SA-V	X		X		X
SA-W	X		X		X
SA-Y		X			
SA-Z		X			
SA-AA	X			X	
SA-AB				X	
SA-AC		X			
SA-AD			X		
SA-AE	X			X	X
SA-AF	X				
SA-AG				X	X
SA-AH				X	
SA-AI				X	
SA-AJ			X		
SA-AK	X	X		X	X
SA-AL				X	X
SA-AM	X				
SA-AN	X			X	X
SA-AO	X	X			X
SA-AP				X	
SA-AQ			X		
SA-AR			X		
SA-AS	X			X	X
SA-AT	X		X	X	X
SA-AU	X			X	X
SA-AV	X			X	X
SA-AW				X	
SA-AX			X		
SA-AY	X				X
SA-AZ	X				X
Total = 51	24	10	11	29	22

Table 5. Average Price Decreases, Polk County Round I

Category	Average Price Decrease (%)	Minimum (%)	Maximum (%)
Enterals	16.89	−81.99	70.07
Hospital beds and accessories	25.58	−4.26	40.36
Oxygen supplies	16.86	6.79	32.39
Surgical dressings and supplies	−20.33	−73.88	27.00
Urologicals	8.20	−458.65	31.01
Overall	4.46	−458.65	70.07

the San Antonio project experienced no change in price or a price increase, and 13 of the 76 goods in Polk County Round II experienced price increases, much like our theoretical models predicted.[21]

To take our analysis further, we tested our prediction that goods with relative demands that are perceived by the firms to be underestimated by CMS (weights that are too low) would experience price increases. This price increase would result from the fact that a firm would increase (decrease) its bid on goods for which CMS underestimated (overestimated) relative demand. Hence, this would inflate (deflate) the resulting prices on goods for which firms had relative demand estimates that exceeded (fell short of) those of CMS. We were able to do this by comparing the weights given to the 130 individual goods that appeared in both Polk County Rounds I and II. Recall that the weights given to the goods in Polk County Round I were based on the estimated relative demand for the goods during the experiment. Conveniently, the estimated demand weights given to the goods in Polk County Round II were based on the demand realizations during Polk County Round I. Hence, if the weights from Polk County Round I exceeded (fell short of) the weights from Polk County Round II, this was a sign of overestimation (underestimation). Therefore, we created an indicator variable to determine if the relative demand for a good was underestimated.[22] Underestimation occurred for 20% of the goods (25 goods) that appeared in both Rounds I and II in Polk County. Using this indicator variable, we then checked for a correlation between price increases and relative demand underestimation. We found that if a good's relative demand was underestimated by CMS in Round I, this significantly increased the probability that the good would experience a price increase as a result of the bidding process. In fact, we found that underestimation increases the probability that a good experienced a price increase by 25 percentage points. Specifically, goods with underestimated relative demand experienced an average increase of $3.95 per unit.

[21] In addition, we calculated a pairwise t-test and found that we could reject the hypothesis that the old fee schedule and the demonstration prices were equal

[22] Demand realizations were not available for Polk County Round II or San Antonio Hence, a similar variable could not be constructed for those rounds.

Table 6. Average Price Decreases, San Antonio Area

Category	Average Price Decrease (%)	Minimum (%)	Maximum (%)
Hospital beds and accessories	22.62	14.22	29.61
Nebulizer inhalants	−10.66	−100.00	34.69
Non-customized orthotics	20.75	3.00	28.76
Oxygen supplies	17.33	6.29	29.75
Manual wheelchairs	20.38	3.78	28.57
Overall	15.37	−100.00	34.69

Table 7. Average Price Decreases, Polk County Round II

Category	Average Price Decrease (%)	Minimum (%)	Maximum (%)
Enterals	N/A	N/A	N/A
Hospital beds and accessories	31.29	21.66	38.45
Oxygen supplies	17.54	12.11	23.43
Surgical dressings and supplies	2.43	−80.00	17.84
Urologicals	−2.97	−162.17	33.79
Overall	8.57	−162.17	38.45

N/A indicates not applicable

Other implications of our model include the possibility of diminished quality of service. First, the fact that a firm wishing to supply a good was "forced" to supply every other good in that category may result in the firm trying to avoid those goods in the category that are not cost effective. Second, as firms game the system, some goods will be under-priced and, hence, winning firms will be hesitant to supply those goods if the price ends up being too low.

Currently, there is no information pertaining to service quality levels. However, there is anecdotal evidence of diminished quality that comes from CMS itself. For instance, in an effort to minimize the negative impact of declines in service quality, quality check site visits of all winning firms have been instituted. In addition, an independent contractor has been assigned to conduct quality assurance surveys of the beneficiaries involved in the competitive bidding experiment. Both efforts on CMS's behalf seem to indicate that CMS believes that the possibility of a decline in quality is great enough to warrant costly checks on both the firm and beneficiary sides of the market. Further problems with the process are evidenced by the fact that some winning firms have attempted to withdraw from the program.

6. Conclusion

The theoretical results found in this paper show that the CMS format will likely result in an inefficient supply of medical equipment, increased prices on a number of goods, and

Table 8. Average Price Decreases, All Sites, All Rounds

Category	Average Price Decrease (%)	Minimum (%)	Maximum (%)
All Sites, All Rounds			
Hospital beds and accessories	26.56	−4.26	40.36
Oxygen supplies	17.51	6.29	32.39
Round I Polk County & Round II Polk County			
Surgical dressings and supplies	−12.63	−80.00	27.00
Urologicals	4.01	−458.65	33.79
Only San Antonio			
Nebulizer drugs	−10.66	−100.00	34.69
Orthotics	20.75	3.00	28.76
Manual wheelchairs	20.38	3.78	28.57
Only Round I Polk County			
Enterals	16.89	−81.99	70.07
Overall	9.22	−458.65	70.07

potential problems for beneficiaries in obtaining equipment. Using preliminary results from actual CMS Demonstration Projects, empirical evidence is provided that supports these predictions. While we applaud CMS's attempts to reduce medical expenditures and its initiative of implementing competitive bidding as a means to this end, we strongly urge a restructuring of the bidding process.

The problem with the CMS process is that the bid scoring and price formulation procedures are inconsistent with the bidding behavior that CMS wishes to induce. That is, overly complex rules for choosing winners and setting prices distort the incentives that bidders face and may actually result in increased prices for some consumers. We believe that the misalignment of the rules with the desired bidding behavior stems from a faulty application of single-unit auction results to a multi-unit setting: a misconception that has even been propagated by Nobel Laureates (see Ausubel and Cramton 2002, pp. 1, 27, for a discussion).

In conclusion, it appears that the initial formulation of the competitive bidding process fails to achieve CMS's goals. However, by initiating competitive bidding in an experimental manner, CMS has allowed for in-depth analysis of its bidding process before whole-scale changes are set in motion. We end by noting that the emerging literature on multi-unit auctions provides a host of alternative bidding formats that do not suffer from the problems identified in this paper (see Cramton, Shoham, and Steinberg 2006). Our suggestion is that CMS develop a descending variant of Ausubel, Cramton, and Milgrom's (2006) clock-proxy auction. In that auction, a first stage of open bidding allows for simple transparent price discovery, while a second round of proxy bidding ensures efficiency. This format is particularly promising, as it eliminates the exposure problem, eliminates the incentives for demand reduction, and mitigates collusion, all *without* distorting bidder incentives, thus increasing the expectation of reduced Medicare prices.[23]

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Small Business Committee Testimony: Gerald Sloan

Thank you Chairman and Committee members for the opportunity to come and share my story and our industry's small business concerns. My name is Gerald Sloan and I am the founder and owner of Progressive Medical Equipment located in Kansas City. My company is defined as a small business by SBA standards and barely so as defined by CMS. We will be celebrating our 10th year of doing business this April. We currently employ 18 individuals that service the 5 county area of Kansas City, the 4 county area of St. Louis, and most counties throughout Central Missouri. Although we specialize in servicing mobility needs, we are a full line DME company that provides among many things, standard items such as Oxygen services, Hospital Beds, and Bath Accessories. This allows us to be a single point of contact for most our referral sources.

I come before you today to tell the story of Competitive Bidding from a small provider point of view. Like many small DME's across the United States, we began the Competitive Bidding process with much trepidation and uncertainty. Although CMS had promised to install safeguards into the system such as requiring a target of 30% small provider participation to protect small providers, we realized that this actually meant thousands of us would be excluded. Additionally, because the program had no transparency in determining winning bids, we felt and many actually realized that they could be excluded without any refutable cause. Any error in processing by the administrators of the program could devastate or eliminate the chances of any provider from participating. CMS recognized that they had made errors and overturned participation for some providers, but many such as Todd Tunison of Summit Medical, a small DME in Lee's Summit, MO were turned away with vague references to inability to meet financial standards but with no specific explanation.

When we began submitting our bids online, our worst fears were soon realized. The system was not ready for submittal of bids. My company was the first to notice and notify the contractor that the system was asking us to bid in zip codes that were not part of the Kansas City Metropolitan Statistical Area. We were also asked to bid on a code whereas no product was available for the code. If we left the area blank, our bid would be thrown out as incomplete. The best guidance we received from CMS was that by filling out "not applicable" our bid *should* be fine. In other words, a guess was dictating our future.

We were also required to bid below the current allowed amount for each code. There were numerous items that we bid that were already priced below our acquisition cost. This requirement seemed grossly unfair. If the project were to be deemed truly fair to the provider, wouldn't it allow us to bid up for products that we have historically lost money on?

In short, the bidding process was poorly run and left much room for doubt. It was difficult enough alone not knowing whether our bids would be good enough to continue with the Medicare program but couple with the knowledge that errors were being made

continuously throughout the bidding, we were left wondering how we would continue with the program despite our preparedness and willingness to do so.

We eventually were selected to participate in 4 of the 5 categories that we bid: Complex Rehab, Consumer Power Wheelchairs, Walkers and Related Accessories, and Hospital Beds. Although we won our bids, I still feel strongly that CMS did not do enough to protect small providers and ultimately favored large national companies. Evidence of this can found directly from the booklet received by Medicare Beneficiaries prior to July 1, 2008 announcing the program and winning providers.

My company, Progressive Medical Equipment, was one of two local providers to win in the Complex Rehab category. The other two winners, Scooter Store and ATG Designing Mobility had never participated in this category in our MSA. To the best of my knowledge, neither is currently doing so. Also, one will find that the Scooter Store, a national provider of Consumer Power Wheelchairs is listed 3 times as a provider to call in our MSA. Everyone else was listed only once.

In the Consumer Power Wheelchair Category, Apria, another national provider was listed 14 times for Power Wheelchairs. Scooter Store, again, was listed 3 times. This means that of the 31 listings for Providers in this category, 17 were these two companies.

The Walkers and Related Accessories shared the same common theme. Of 33 listings in the booklet, Lincare, a large national company is referenced 14 times. Scooter Store has 3 listings.

As for the Hospital Beds and Related Supplies category which features 49 listings, Apria is listed 14 times, Lincare 14 times, and Scooter Store 3 times. In other words, 31 of 49 listings, or 63%, of the listings were divided among these 3 large national providers. No small provider was given more than 1 reference per category.

I would also like to point out that Scooter Store won in every category in our MSA. CMS has been adamant about the quality of service not being compromised in this acquisition program. But one must ask, how did a company that has never provided Oxygen Services, Hospital Beds, Complex Rehab, etc., let alone in our MSA, be selected to do so?

Additionally, as recently as 2007 Scooter Store settled with the Department of Justice for the sum of $17 million dollars to ward of the conviction of Medicare fraud. Apria did the same for approximately the same amount in 2005. Lincare settled in 2006 for $10 million to stave off convictions of violating the anti-kickback laws. All the companies denied any wrong doing by settling. But the implication is quite clear. You don't pay this kind of money if you didn't do anything wrong.

As directed, CMS did make attempts to inform Medicare Beneficiaries of the DME benefit changes. The attached letter and booklet show the extent of their efforts. Both the letter and booklet are confusing and misleading. None of the material addressed the

capped rental issues that surrounded oxygen. We fielded more than 25 phone calls in the first few days of competitive bidding from our customers confused about the changes in the program. At one point, we were so swamped with calls that we couldn't handle our regular business.

Perhaps the greatest and longest term ramification of the Competitive Acquisition program for my company rests in our Oxygen Service. As you may be aware, Congress passed a 36 month cap payment for Oxygen Concentrator reimbursement. The first of the capped rentals were scheduled to occur in January, 2009. When we were submitting bids for oxygen, we were still waiting on a final rule of what would happen after the 36 month cap. Questions such as, "who would own the equipment and what kind of service calls would be reimbursed", were left unanswered by CMS. Without this knowledge, I felt that as a small provider with very limited numbers of Oxygen referrals a month it would be unwise for me to gamble that the terms of the cap would be financially feasible for us. Therefore our bid was higher than the accepted bid amount and we lost the bid.

In anticipation of losing the Oxygen category, we began to reduce our marketing in this area right after we submitted our bids. By July 1, 2008 we were down to 1 to 2 referrals a month—down from 6 – 10 referrals. Just a few years ago we averaged 75 – 100 Oxygen clients. Our number currently stands at 27, 24 of whom are capped out with no reimbursement for our service. So in short, our Oxygen service is dead because of Competitive Bidding. Not only do we lose, but so does our community who depends on us for very personalized and committed service. Customers who were disgruntled with the service they received from large national companies switched to us regularly. Stealing customers from the national companies was easy for us because none could care for their customers like we could. Competitive Bidding provided the perfect venue for large companies to eliminate real competition from small providers.

Another major concern with the Competitive Acquisition program was the inability to adjust bids because of economic factors. We made bids in the summer of 2007, long before the price of gas began its well know spike. By the time the program started in July of 2008, the price of gas had doubled. The effect of the rise was not only felt in our fleet, but in the price of our products as well. Every supplier we used began adding fuel surcharges to our shipments. Some started requiring minimum orders before they would ship. This had a devastating effect on our ability to maintain the margins necessary to remain profitable. Thankfully, the program only lasted two weeks but one has to wonder how long could we have lasted in a three year contract under such conditions?

Finally, I would like to comment on CMS's willingness to listen to providers regarding the Competitive Acquisition program. Although they paid lip service to creating a committee to guide them, in reality the PAOC or Program Advisory Oversight Committee was never given much consideration. The original committee was disbanded and a new one was formed in the last three months. Of the 17 members of the committee, only 4 are providers of DME services. Even with letters of recommendation from the Mid-West Association for Medical Equipment Suppliers and Senator Roberts plus my experience with round one, I was not ask to help make the program successful. I'm

confident that there were many others who volunteered with equal or better qualifications that were also denied. It appears that CMS simply does not care to implement a fair and reasonable program.

In conclusion, I would like to say that the DME industry has been attacked by CMS and Congress for too long for problems we did not create. Fraud has been the ballyhooed cry to justify this persecution. I am before you today to testify that the guilty party is not our industry but is CMS. CMS is charged with maintaining program integrity, yet they continue to allow unscrupulous and nefarious criminals access to Medicare Provider numbers. Even when given a mandate to create a new program designed to cut down on fraud, they allow contracts to go to companies that have been investigated for fraud and who have paid settlements. They have proven time and again, that they are poorly managed and cannot deliver program integrity. Yet we are to believe that they have small business interests in mind, that despite no transparency in the process we are to trust them with decisions that affect thousands of companies and tens of thousands of employees and their families. I come before you to ask the Small Business Committee to find a way to strike down this program before it hurts anyone else.

TESTIMONY OF ALAN S. ROUTMAN, M.D.

ON BEHALF OF

THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

ON

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

BEFORE THE U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SMALL BUSINESS
Subcommittee on Rural Development, Entrepreneurship and Trade

February 11, 2009

Testimony of
Alan S. Routman, M.D.

On Behalf of
The American Association of Orthopaedic Surgeons

On

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

Before the Subcommittee on Rural Development, Entrepreneurship and Trade

February 11, 2009

Good afternoon Chair Schuler, Ranking Member Luetkemeyer, and members of the Subcommittee. I am Dr. Alan Routman, a fellow of the American Academy of Orthopaedic Surgeons and Vice Chairman of the Board of Managers of the Physicians Outpatient Surgery Center in Fort Lauderdale, Florida. I am here on behalf of the American Association of Orthopaedic Surgeons (AAOS), which represents more than 17,000 board-certified orthopaedic surgeons.

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

With that said, I would like to highlight, what we believe to be the unintended consequences of applying rules meant for retail DMEPOS suppliers to physicians in small practices across the country who provide certain DMEPOS as part of providing high quality care to their patients. It is important to note that we are talking about physicians who supply DMEPOS *only to their patients*, not to the general public. And because many of our physicians who provide DMEPOS to their patients are essentially small businesses and many provide those items to their patients because they are the only "supplier" in rural areas, we are especially appreciative of your willingness to discuss this issue today.

* * *

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

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

(1) Durable Medical Equipment- As you are probably aware, physicians are not allowed to supply most DME to patients because of the Stark self-referral regulations. However, because some DME is so important to a patient's ability to safely leave the physician's office- and so important for preventing further injury, an exception from the Stark prohibition was created for several items. In the area of orthopaedic surgery, this exception includes crutches, canes, walkers, and folding manual wheelchairs. Physicians are able to provide these items to their patients if the arrangement fits within the Stark in-office ancillary exception.

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

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

surgeons provide to their patients. In addition, Congress did not authorize CMS to include prosthetics as part of the competitive bidding program.

With that groundwork laid, I'd like to take you through some of the concerns that we have regarding new and revised rules pertaining to the provision of DMEPOS to our patients. While I know that our focus here today is the competitive bidding program, I'd like to give you the full picture of how the provision of DMEPOS to our patients is becoming increasingly difficult. Specifically, I would like to address the quality standard *accreditation* process for physician-suppliers.

CMS has signaled that it might implement an unnecessary requirement that physicians be accredited in order to provide DMEPOS to their patients. This threatens to interfere with the continuity of patient care and the primacy of the patient-physician relationship, increase the administrative burden of participating in the Medicare DMEPOS program, and exacerbate the financial stress of many physician practices delivering care to Medicare patients.

DMEPOS QUALITY STANDARDS & PHYSICIAN-SUPPLIERS

In order for a physician to be able to provide allowed DMEPOS to their patients and bill Medicare for those products, the physician must not only be enrolled to participate in Medicare as a physician- but must also enroll as a DMEPOS "supplier." The rules make

no differentiation between large retail DMEPOS suppliers and physicians who are also serving as DMEPOS suppliers solely during the course of caring for their patient.

I would personally like to thank the members of this subcommittee for addressing this issue in the last Congress. In May 2008, you held a hearing, at which the AAOS testified, looking into the flaws of the DMEPOS competitive bidding program and accreditation requirements. I'd like to thank Committee Chair Velazquez, Chair Schuler, and everyone else who attended that hearing for bringing focus to the impact of these requirements on patients and small practices- all resulting in several changes made to the program when Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Specifically, MIPPA Section 154(b) expands the Secretary's authority to address these patient access concerns and has the potential to assure greater access to high quality and necessary DMEPOS at the point of care. MIPPA Section 154(b) amends 42 U.S.C. 1395(m)(a)(20)(E) by adding the following provisions:

> (ii) in applying such standards and the accreditation requirement . . . with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specific by the Secretary, furnishing such items and services-
>
> > (I) such standards and accreditation requirement ***shall not apply*** to such professionals and persons ***unless*** the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

> (II) the Secretary ***may exempt*** such professionals and persons from such standards and requirement ***if*** the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

In response to this Congressional directive, in September 2008, CMS exempted physicians from the DMEPOS accreditation deadlines. However, in several subsequent communications, CMS has signaled its intention to subject physicians to these requirements in the future. It is our strong belief that the Secretary of HHS should exercise the authority granted in MIPPA to exempt physicians and licensed health care professionals from the quality standards and accreditation requirement considering the licensing, accreditation, and other quality requirements that physicians and licensed health professionals must meet.

THE QUALITY STANDARD ACCREDITATION PROCESS

As I mentioned, we are concerned that CMS is indicating that physicians will still require accreditation for physicians to be DMEPOS suppliers. We acknowledge and share Congressional and CMS interest in ensuring Medicare beneficiaries receive high quality care, supplies, and service. However, we are equally committed to ensuring that patients have access to the care and supplies that they need in a safe, efficient, and timely manner. Unfortunately, our members are finding it increasingly difficult to deliver DMEPOS to our Medicare patients.

The provision of these items is limited by law and the type of medicine that orthopaedic surgeons practice. Therefore, in most cases orthopaedic surgeons are submitting claims for a very small number of DMEPOS items. However, in order to go through the accreditation process, physician practices will be charged approximately $3,000 *per location* to be accredited as having met the Quality Standards. This only makes it increasingly difficult for physicians to participate, especially in the context of unpredictable payment for physician services and rising costs of providing care. We have spoken to some small practices that provide so little in terms of DMEPOS that total Medicare claims for the year are only $1,500- yet for those patients who need these items, it is a critical service. I suspect for some practices, that number is even lower. Ultimately, this process will result in a net loss for many physician practices, many in rural areas, across the country.

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

I'd like to share with you the personal experiences that I have gone through trying to ensure that I can get my Medicare patients the care that they need and deserve. Over the

course of the last year, I have been jumping hurdle after hurdle, attempting to get my DMEPOS supplier number, so that I can submit claims for the DMEPOS that I deliver to my patients.

In submitting my paperwork to the Medicare contractor assigned to Florida to receive my DMEPOS enrollment number, I was repeatedly denied because I, as a physician, have not been accredited as being qualified to provide items like crutches and splints to my patients- even after decades of medical training and practice. CMS even continued to deny me a DMEPOS enrollment number *after CMS exempted physicians from the most recent DMEPOS accreditation deadlines.*

Because of this, I have not been reimbursed by Medicare for DMEPOS for the last 12 months, which has resulted in several thousand dollars of unpaid claims- which – as you know- for a small business and solo practitioner is a tremendous amount. During this time, I have continued to provide Medicare patients with the DMEPOS products, because they need it, and because I have hope, heightened from the attention that you brought to this issue last year, that I will eventually be compensated for the reasonable and necessary care that I have delivered.

Recommendation

I'd like to leave you with a recommendation regarding physician provision of DMEPOS in the Medicare program which will ensure patient access to necessary items while

maintaining the integrity of the program, which I know is a goal shared by all of the stakeholders you've heard from today.

We'd seek your support in recognizing that physicians are already trained to provide and administer DMEPOS to patients. The AAOS continues to work with CMS to assure quality in the Medicare program. We firmly believe that, given the complexity of today's health care environment, steps must be taken to ensure that there are not unnecessary or duplicative efforts required of program participants that would discourage patient access to care. In terms of providing public confidence that the providers and suppliers of DMEPOS are trained and qualified, we believe that professional society credentialing and training processes and state regulation of practitioners already provide many of the necessary safeguards in this area.

While we understand the need for a process of this nature for commercial suppliers, **we ask *not* that physicians and health care professionals be exempted from having to be accredited, but rather- that they be deemed as having met the requirements of accreditation once they are licensed or credentialed to practice medicine under state law.**

SUMMARY

The quality and accreditation requirements applicable to physicians and health professionals should balance the costs of compliance against the affected physician-

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

I would like to thank you, Chairman Shuler, ranking member Luetkemeyer, and members of the Subcommittee for the opportunity to speak to you this afternoon, and I am happy to answer any questions that you might have.

The Impact of Competitive Bidding on the Market for DME

By: Brian O'Roark, PhD and Stephen Foreman, PhD, JD, MPA

February 18, 2008

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The Impact of Competitive Bidding on the Market for DME

By: Brian O'Roark, PhD[1] and Stephen Foreman, PhD, JD, MPA[2]

February 11, 2008

Summary

After two demonstrations limiting the supply of DME through bidding of franchises, CMS has determined to extend bidding for DME franchises to ten MSAs in 2008 and another 70 in 2009. This paper investigates the potential implications of the CMS efforts. We conclude that while artificial limitations on supply of DME may produce what CMS characterizes as short-run "savings," the payments may represent payments for future market power by suppliers. DME is a competitive market both in theory and in practice. Artificial limits on supply will produce artificial shortages and access problems in the intermediate run (five to 20 years), will ultimately increase price and reduce social welfare and will, more likely than not, result in monopoly profits for the successful bidders that CMS will have little incentive or ability to regulate. The artificial limits on competition will create substantial dead weight loss and misallocation of scarce resources. Jobs will be lost in competitive firms and there will be severe employee dislocations and inefficiencies. Given the small size of national spending for DME and the lack of DME cost increases (particularly in comparison to hospital and physician care and prescription drugs), there does not appear to be much in the way of rationale for the franchise bidding scheme from a public benefit standpoint. Capture theory suggests that the competitive bidding scheme may well result in inefficient and questionable future relationships between CMS and the successful bidders. In truth, the market for DME is already more concentrated than the nature of the industry would suggest is natural. CMS should take steps to enhance competition in the market for DME rather than adopting artificial limitations.

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1. INTRODUCTION

Traditionally, the Centers for Medicare and Medicaid Services (CMS) has paid for durable medical equipment, prosthetics, orthotics, and supplies (DME) based on "reasonable cost" as defined by CMS.[3] From 2000 to 2002, CMS conducted a competitive bidding demonstration for DME. Unsuccessful bidders were excluded from the market. The demonstration reduced Medicare costs 17% to 22%. CMS plans to extend the competitive bidding program to 10 MSAs in 2008 and to 70 more in 2009.

As the largest purchaser of durable medical equipment and supplies in the United States, CMS justifies the proposed competitive bidding plan in terms of market efficiency. CMS claims that by bidding for the ability to provide medical equipment, the lowest prices will be assured, thereby garnering cost savings for Medicare.[4] However, the competitive bidding policy contains the seeds of serious long-run unintended consequences: Any short-run cost savings[5] will be more than offset by long-run increases as successful bidders gain market power over time.

Basic economic theory, as well as past experience, opposes restricting the number of suppliers in a market – for good reason. First, interference with competitive markets inevitably leads to higher, not lower, prices. Indeed, the customer base for medical equipment and supplies is expected to grow dramatically during the next 20 years. Artificially restricting the market now will lead to substantial market failure in 10 to 20 years. Second, government intervention in the market for DME will produce reduced efficiency, fewer transactions, and job losses. Third, the

[3] Indeed, it is strange why CMS has determined that there is a problem with DME spending when CMS fixes DME price.
[4] In 2006, the average Medicare premium increased 13.2%, making the lure of reducing medical costs at any level quite attractive (Health Inflation News).
[5] Indeed, it is not clear that the results of the demonstration sites are generalizable. Also, it is more likely than not that the successful bidders were paying a one-time premium in order to gain a future monopoly. Rather than "savings" the short term reductions are probably in the nature of payment for a franchise fee.

health care industry generally is characterized by special interest capture. This will occur with DME just as it has occurred with hospitals and health insurers.

We will conclude by providing a look at the health care market itself. Durable medical equipment spending is a very small part of the overall health care spending. This calls into question why CMS is focusing on the DME market rather than on other aspects of health care spending that are clearly out of control.

2. COMPETITION ALREADY EXISTS SO WHY MESS WITH IT?

United States antitrust laws promote and maintain competition in the marketplace. Generations of economists and businessmen have explained the benefits of competition and the position of the U.S. in world markets may be a result of this understanding. Mergers of firms are scrutinized by the Department of Justice (DOJ) and the Federal Trade Commission (FTC). Artificial limits on competition are so serious that collusion to limit competition is a criminal offense and may result in the award of treble damages.

There are many reasons why competition is desirable. For starters, prices tend to be lower and consumer options greater. More generally, competition maximizes total "social welfare."[6] Often, these desired outcomes run counter to the wishes of business. Competition is a difficult environment in which to work. Costs must be controlled, prices tend to be forced down, and profits tend to be reduced. This is good for consumers. While it is difficult for producers, competition forces them to do their best. In this environment everyone gains.

The essence of a competitive market is (1) many small sellers, (2) homogenous products, (3) perfect information regarding quality and price and (4) free entry and exit. The market for medical equipment and supplies is at least workably competitive if not perfectly so.

[6] When economists use the term social welfare they are speaking of the greater good for everyone.

There are certainly "many" DME suppliers, most of them small, particularly in comparison to large health insurers and for that matter the Center for Medicare and Medicaid Services itself. A quick internet search of business directories produces a 37-page directory for medical equipment and supplies firms. The Medicare approved supplier search engine has so many suppliers for a five state region that the states are divided for search engine use. In April 2006 there were 166,000 active suppliers registered with the National Supplier Clearinghouse.[7] By anyone's classification, this is more than enough suppliers to categorize the industry as competitive.

Medical equipment and supplies are produced in accordance with published specifications. As noted in CMS' Booklet on Durable Medical Equipment, "A supplier enrolled in the Medicare program will have a Medicare supplier number. Suppliers have to meet strict standards to qualify for a Medicare supplier number." Prices for equipment and supplies are (or can be known) at the time of purchase. Accordingly, medical equipment and supplies represent relatively homogenous products – and information regarding quality and price is well known.

For the Medicare program, beneficiaries pay 20% of Medicare approved medical equipment costs (after satisfying a deductible) and CMS pays 80%. Medical equipment suppliers accept CMS payment as payment in full and do not balance the bill. In essence, CMS regulates Medicare price – but it would not have to do so. In any event, price is known.

Finally, entry into the medical equipment and supply market is relatively easy. CMS approval for medical equipment suppliers is straightforward and reinforces product homogeneity and information accessibility.[8] Suppliers must show that they:

- fill orders from their own inventory or under a contractual arrangement,
- oversee delivery of equipment,

[7] http://www.cms.hhs.gov/competitiveacqfordmepos/01_overview.asp
[8] http://oig.hhs.gov/oei/reports/oei-04-99-00670.pdf

- answer questions and complaints from beneficiaries,
- maintain and repair rental equipment,
- maintain a physical address at the business site,
- comply with State and Federal licensure requirements,
- honor warranties on equipment,
- accept the return of substandard equipment,
- disclose consumer information (a list of standards) to beneficiaries,
- comply with ownership disclosure provisions of the Social Security Act,
- have appropriate liability insurance.
- comply with Medicare law,
- make no material misrepresentations on their application,
- provide documentation of compliance with standards to CMS upon request,
- notify beneficiaries that they may rent or purchase certain items,
- ensure application is signed by someone whose signature binds the supplier,
- agree not to transfer or reassign a supplier number,
- have a business phone at the facility, and a listing in the phone directory,
- agree not to telemarket to beneficiaries, except in limited circumstances, and
- receive payment in their own name for drugs used with DME.

While lengthy, these standards are not burdensome. In addition, CMS will soon require all suppliers to be "accredited" by an approved accreditation organization – a requirement that was originally set in place as part of Round 1 of competitive bidding. Other than capital investment or, in some cases, payment of royalties, entry into the market is relatively burden free. Exit from the market is equally easy.

In short, the market for medical equipment and supplies is both theoretically and practically competitive and without government intervention, could reasonably be expected to be so for a long time. Regulating this industry by reducing entry fundamentally changes the nature of the market, and while government price controls are viewed as a way around the high priced nature of non-competitive markets, history does not provide support for such a view.

DEREGULATION (NOT MARKET RESTRICTION) PROVIDES ACCEPTED BENEFITS TO CONSUMERS

The trend in industries over the past 20 years has been one of deregulation. The economic literature is replete with studies that show consumer benefits flowing from deregulation. If an industry can behave competitively, deregulation helps to establish lower prices and greater availability of products to promote consumer welfare. Prices are lower and service is better. Deregulation in many industries has shown to be a tremendous success in terms of price reduction. For example, Crandall and Ellig (1997) show that in the market for long distance telephone calls 10 years after deregulation customers were saving between 40 and 47% over the regulated market. Airline fares had dropped 27%. Truck shipping costs had dropped between 27 and 57% and railroad rates had dropped 44%.

COSTS OF REGULATION

More consumer choices also lead to preferred outcomes. In competitive markets, firms are driven to reduce costs. The least cost provider has a competitive advantage. Understandably, sellers would like to have protection from competition. This is why they seek trade barriers against foreign firms, and why they expend so many resources attempting to obtain artificial barriers to entry.[9] Why are artificial barriers so bad? First, firms with market power do not have incentives to innovate and to take other steps to keep prices down. Equally important, when prices rise the number of people who can afford the product declines. From an economic standpoint higher prices means less trade and poorer economies. In health care there are practical problems: reduced trade means less access to needed health care.

[9] This is normally referred to as rent seeking in the economic literature.

The law of demand tells us that as prices go up, the amounts people are willing and able to buy fall. This creates what economists refer to as a "dead weight," or welfare loss. These losses are particularly poignant in areas where competition is eliminated. To artificially limit competition is to make a conscious decision to increase dead weight loss. Maybe not right away, but just as soon as producers determine that there are no reasonable alternatives to their products.

To prevent shortages in artificially constrained markets, one of two things must happen. The first, and the most efficient, is that prices must go up. However, as noted above, CMS fixes DME price. After exit of a large number of firms from the market, suppliers of DME will demand price increase. Thus, if we want to maintain the future provision of medical supplies, CMS will have little choice but to agree to price increases.[10] The other, and far less preferable option, is that government will have to subsidize the industry so they can afford to keep prices low. This works against the purpose of the bidding process, which, if you recall is to keep prices down. The subsidization merely reallocates the cost to another line in the budget.

Moreover, holding prices artificially low causes other distortions. Consumers do not properly value such goods and services with artificially low prices, and tend to over consume these items. For example, Lutz and Davis (2007) showed that welfare losses are enormous in the natural gas industry due to the price controls. The welfare loss for natural gas is also substantial because consumers who most value the goods may not necessarily be served. This is similar to the findings of Glaeser (1996) who notes that when prices are regulated, the wrong people get goods and services. In other words, goods are not allowed to flow to those people who value them the most.

[10] This follows the pattern where firms and regulators have been powerless to deal with recent increases in the cost of health insurance.

Katsoulucos and Ulph (1994) explain that in an oligopolistic industry[11], losses from public welfare rise. Firms spend substantial amounts to maintain a protected position. Additional welfare losses occur as regulators attempt to push prices closer to marginal cost.[12] Lower price is not what oligopolistic producers' desire, so they typically lose their incentive to control cost, particularly if price is regulated. This process, sometimes called "gold-plating," results in excessive spending that the regulator has no incentive or ability to police. Regulators rely on the premise of reasonable return when setting prices in a regulated industry. According to the FTC v. Hope Natural Gas ruling[13] a dual standard for reasonableness is set where earnings should be based on what a similar firm in a non-regulated industry might earn. The second part of reasonableness is that earnings should be enough to add to the capital stock thereby allowing the firm to serve its customers. If firms have no incentive to keep costs low, the regulator, relying on the Hope Standard, will allow prices to rise to maintain the reasonable rate of return (Wood, 2004). Thus, as Katsoulucos and Ulph (1994) conclude, regulated firms do not put enough resources into their research and development as this might cause costs to fall.

The CMS competitive bidding scheme will, at best, artificially create oligopoly markets for the supply of DME. The conduct of the DME suppliers can be predicted to follow the pattern shown for oligopolies by Katsoulucos and Ulph.

Regulations also tend to lead to "x-inefficiency" (Leibenstein 1973). X-inefficiency occurs because producers have little incentive to combine their inputs in an output maximizing fashion. Once the industry is effectively regulated, the monopoly provider will begin to seek rate

[11] Oligopolies are industries where there are a few suppliers of a good. Oligopoly theory is complex, and incorporates a significant number of variations on firm behavior. Carton and Perloff (2005) provide a comprehensive examination of oligopoly theory.

[12] In a perfectly competitive market, price will equal marginal cost. That is the customer is only willing to spend what it costs to produce a product. If the price is higher than marginal cost the consumer can go elsewhere to purchase the product at a lower price because of the large number of sellers.

[13] The Hope Standard is based on the ruling a the courts in FPC v. Hope Natural Gas in 1944.

increases because they are no longer forced to adhere to strict budgetary restraints that prevail in competitive markets.

Finally, regulation clearly reduces the incentive to innovate. The examples of the natural gas and airlines industries show that many unexpected innovations occurred after those industries were deregulated. The "hub systems" that developed after deregulation increased the ability of these industries to move product faster. Additionally, the telephone industry now has what seems like an infinite number of options available for the consumer; however, these options only became available after deregulation (Crandall and Ellig). Regulation of the US medical equipment and supplies industry (which could be fairly characterized as innovative) threatens to bring with it a lack in innovation.[14]

In short, CMS claims that increased market intervention in DME will produce "savings." This contention flies in the face of decades of study, empirical observation and economic theory. Market deregulation – not increased regulation – s more likely to create cost savings which will lower prices.

MARKET CHANGES: AN INCREASE IN DEMAND AWAITS

The population in the U.S. above the age of 65 is projected by the U.S. Census Bureau to increase to 20.7% of the population by 2050. This is shown in Table 1. Over the same time, the percentage of people over the age of 85 is expected to increase from two percent to five percent of the population. With increases in technology, life expectancy is also becoming longer. This means the demand for medical equipment and supplies will grow dramatically. Increased

[14] Indeed, artificial regulation of the DME market could well result in moving research and development in yet one more industry where the US has held a worldwide lead to other countries.

demand coupled with reduced supply is a recipe for huge price increases. This is basic economics. Economies ignore these precepts at their peril.

Table 1: Percentage of the U.S. population over the age of 65

Year	Percentage of Population
2010	13%
2020	16.3%
2030	19.6%
2040	20.3%
2050	20.7%

SOURCE: U.S. Census Bureau population projections

Price controls inevitably lead to market shortage. Assuming price controls are successfully set and maintained below a market determined price[15], there will be those who get the product, whether it be healthcare, gasoline, an apartment, or bread, who are made better off.[16] Meanwhile, those who are not fortunate enough to acquire the good or service under the price control must resort to other means such as waiting in lines, bribery, or worse.

The simple solution for these shortages is to let the price rise. However, if that is not economically or politically palatable, another solution is to increase the available supply of a good. While governmentally provided production is historically inefficient and market solutions are preferred, government could instead improve the market condition by reducing barriers to entry.

Classically, when governments regulate price, sellers compete based on quality and service. The market for DME currently reflects this. However, CMS has proposed to restrict even this limited quality and service competition in the market for DME by competitively bidding "franchises" to Medicare suppliers. As has been pointed out though, limiting supply is a

[15] This assumption presumes regulators are able to accurately determine what the market price would be without their interference. If, as in the case of the minimum wage, the market sets prices higher than the price control, the price control is useless.

[16] This happiness of course, assumes that product quality does not change, which is itself a heroic assumption.

recipe for disaster.[17] Economies of scale are important aspects of production, but in a market where competition is alive and well, and small firms make up 85% of the market, economies of scale would not be a reasonable justification for limiting entry in this case. Otherwise the market would adjust without the need for external limitation.

FRAUD

CMS now claims that the competitive bidding process is needed to eliminate fraud from the DME program; however, competitive bidding processes are rife with distortions related to information asymmetry and with differences in quality. Despite the assertions of eliminating fraud, there is no evidence that if fraud exists competitive bidding will eliminate it – or, for that matter, that the level of any existing fraud justifies the increased costs and inefficiency that will occur when the remaining DME suppliers are given market power.

Wolinsky (1995) has analyzed the markets for "credence" goods. These are goods for which the seller has information that the buyer does not. Additionally, the buyer may never know whether the product he or she purchased is actually provided or that it has been provided properly since the buyer is not an expert. Wolinsky shows that the asymmetrical information between buyers and sellers is likely to lead to a mark up in costs.

This would not be mitigated by a bidding process. In fact, Kamerschen (1998) shows that increased market power, which will be the case as a result of the bidding process, is relevant to determining the potential for practicing fraud. Put another way, if some DME suppliers are currently practicing fraud and are not discovered, they have a competitive advantage. We should expect that they would also be willing to factor their advantages derived from fraud into their

[17] A quick review of one regulated industry supports this. Cable television is a heavily regulated industry where government prohibits entry. According to surveys, in the cable television sector, price and service satisfaction are ranked among the lowest industries (American Society for Quality).

bids – which would make them more likely to be the successful bidders. And, with market power derived from their successful bids they would be even less likely to be discovered. If they were discovered it would be harder to replace them.

Whitford (2007) notes that there has been scant attention paid to the prospect for collusive behavior in public bidding. If formation of a collusive cartel is a goal of colluding firms, they will affirmatively embrace competitive bidding because collusive behavior becomes easier when there are fewer firms to monitor within a cartel. In fact, Whitford continues, without controlling for the costs of preparing a bid, which includes asymmetries of information, fewer bids are likely to be made. According to Bajari and Fox (2005), collusion is likely in the bid structure for U.S. mobile phone spectrum auctions even with the threat of a bidding war. Similarly, awarding DME franchises runs the risk of producing price collusion at a level that would be impossible under the current DME supplier structure where thousands of firms compete.

Furthermore, the allegations of fraud are vague and unquantified. Even if there is some fraud[18] (not surprising in an industry of this size) there is no indication that its magnitude is in any way material. Observers have concluded that there is approximately five to 10 % fraud in the food stamp program. Despite this, we have neither eliminated the program nor competitively bid franchises to grocery stores. Overall, when most of the benefits of a program are getting to beneficiaries we cannot justify terminating the program or injecting massive inefficiency into it merely to eliminate fraud. While fraud is always a problem, inefficiency can be a greater problem, particularly when it takes the form of distorting the entire structure of an industry.

[18] CMS pervasively regulates DME firms. If there is fraud CMS has the resources and the ability to root it out. Creating a concentrated market for DME based on this fraud would be a classic case of two wrongs not making a right.

Crawley and Whitford (2007) show that imperfect competition limits the success of bidding processes. The idea that bidding for DME franchises will eliminate the bad behavior of firms in the DME industry is particularly ludicrous. If CMS is concerned about bad behavior it can and should deal with it directly.

Regardless of the reason, the CMS barrier to entry for DME will work against the objective of keeping prices under control. A large company that simply gets larger to address the needs of a growing market, while small businesses are driven out, can be expected to become the epitome of inefficiency. It will have no need to innovate, and in healthcare, innovations are vital. There will be no need to control costs. Unless regulators become vigilant, and they typically have little incentive or ability to do so, the same problems that plagued utility providers will come to afflict this industry as well.

3. CONSEQUENCES OF GOVERNMENT INTERFERENCE

Given that full price and quality competition in the market for medical equipment and supplies would produce gains for all and that such competition could be achieved in this market, what impact can be expected from the competitive bidding that has been proposed?

The Theory of the Second Best suggests that government intervention to deal with imperfections in markets usually works to reduce social welfare rather than improving it. In the current situation what this implies is that if there are problems in the market for medical equipment and supplies based on the lack of price competition, further limits on competition by eliminating competitors from the market will do more harm than good.

Medicare's fixing price schedules, forbidding balanced bidding, and separating consumer responsibility for price from the consumer's (and the doctor's) decision process, will further

undermine the incentive to work towards a viable solution. Indeed, rather than limiting competition by competitively bidding Medicare medical equipment and supply franchises, Medicare should investigate mechanisms that will restore full price competition to the market and reduce the dead weight losses that already exist.

Two hundred years' experience with industry and recent experience with health care insurers shows that firms in concentrated industries cut production and raise price. For example, after 15 years of merger and consolidation, health insurance in the U.S. is now dominated by large health insurance firms with monopoly power. Aetna-US Healthcare, United and Anthem-Wellpoint each provide health insurance to tens of millions of people. Local Blue Cross firms provide health insurance to millions. What have we learned from this experience? They have used market power to increase health insurance premiums by double-digit amounts for years. Their administrative costs and profits are now approximately 20% of premiums – up from 8% fifteen years ago and they enjoy tens of billions of dollars of profits on an annual basis.

The reduction of competition in the market for medical equipment and supplies will follow a similar pattern. After reducing the number of firms in the industry, the remaining firms will raise prices, will increase their administrative costs and inefficiency and will increase profits. Having bid many of the small firms out of the market, there will be no alternative suppliers available to accomplish price reductions. The additional burdens imposed by the concentration will far outweigh any temporary gains in price or in administrative convenience.

FURTHER UNINTENDED CONSEQUENCES

Many, if not most, public policy changes have unintended consequences. In this case, the unintended consequences of public policy loom large. As has been detailed, increasing

concentration in the medical equipment and supply industry will result in increased prices and administrative cost inefficiencies. In the future when prices increase, medical equipment and supply prices will spin out of control – just like health insurance costs have done. Medicare beneficiaries currently pay 20% of the cost of their medical equipment and supplies. Medicaid pays the cost for patients who do not have Medicare. Some patients pay for equipment and supplies out of pocket.

When the patient (or their family) cannot afford the cost of medical equipment and supplies in the home setting, he or she is a candidate for admission to a long-term care facility. Long-term care is quite expensive, in excess of $60,000 per year per patient. Even a small increase in long-term care admissions will result in huge increases in medical care costs, all of which are inefficient because it will relate to misplaced public policy.

In short, before implementing any competitive bidding scheme that reduces competition in the market for medical equipment and supplies, Medicare and Congress should carefully calculate the potential additional costs that may be attributable to future price increases and increased long-term care demand.

EMPLOYMENT

Yet another troubling aspect of this proposal is that the reduced number of competitors will lead to the loss of employment in this industry. According to the CMS, 85% of the DME suppliers are small. Based on the CMS final rule[19], the industry classifications that will be most affected by this ruling would be NAICS 446110 – Pharmacies and drug stores, and NAICS –

[19] http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1270f.pdf

532291, Home health equipment rental.[20] The concentration ratios[21] of these two industries reveals that they are already more concentrated than a fully competitive industry would be. Specifically, the top four firms in the Pharmacy and Drug Store sector control 52.8% of all sales and account for 59% of the paid employees.

The next four firms in this industry comprise only 8.2% of sales and 62,110 employees. The next 12 largest firms only hold 4.6% of the market, and add 36,617 employees. The next 30 firms add only 2.8% to sales, while adding only 17,724 workers.

The top 4 firms in Home Health Equipment Rental control 68.2% of sales and 60% of all paid employees. The next four firms add 6.5% to total industry sales and 2,214 workers. The next 12 largest firms add 4.2% to sales, and 1,076 workers. The next 30 largest firms comprise 5.1% of sales, and add 1,727 workers. These data are shown in Table 2.

As a whole, these industries are already somewhat top heavy. The bidding process will inevitably add to this concentration. Early results confirm this. The bidding process has reduced the number of small businesses who can profitably enter this industry. While all firms were encouraged to submit bids, of the 15,000 firms expected to submit bids, only 2,200 were in a position to do so. More concentration, as has been shown in virtually every analysis, results in higher prices.

On the jobs front we can safely assume that in the initial phases of this bidding process, as small firms get pushed out of the market, there will be a loss of jobs. Using figures from the NAICS report, we can deduce that job losses will occur in the smaller firms. While limiting this inquiry to two NAICS numbers is probably an improper generalization of competitive impact, it

[20] NAICS stands for the North American Industry Classification System. This is the way the U.S. Census Bureau classifies industries. The analysis here is based on the 2002 NAICS data which is the most recent available.
[21] Concentration ratios are calculated by taking the percentage of sales by the top n number of firms and dividing it by the industry total. The Census bureau reports n as the top 4, 8, 20, and 50 firms.

is consistent with the way that CMS has evaluated impact. If the top 50 firms in each industry survive unscathed, and the remaining firms are not able to compete, there is a potential for job losses in the drug store industry of 205,600 workers and in the home health equipment rental industry of 5,670 lost jobs. These individuals will likely find other jobs, probably with the very large DME providers, but the disruption itself will be significant, inefficient, and unnecessary. Even if these assumptions are reduced to 10% of this number, this would amount to over 21,000 jobs lost.

TABLE 2: Concentration ratios for sales and Employment numbers

	Pharmacies and Drug Stores		**Home Health Equipment**	
	Concentration of sales (%)	Paid employees	Concentration of sales (%)	Paid employees
Top 4 firms	52.8	461,296	68.2	16,269
Top 8 firms	61.0	523,406	74.7	18,483
Top 20 firms	65.6	560,023	78.9	19,559
Top 50 firms	68.4	577,747	84.0	21,286

Source: U.S. Census Bureau, 2002 Economic Census

SERVICE

Service is or should be another major concern related to CMS' competitive bidding for DME franchises. Franchise bidding schemes contain built-in incentives that will reduce service to consumers, either through the pricing process itself, or in the event of what economists call "the winner's curse."

CMS already fixes prices in the market for durable medical equipment. In a competitive market where price is fixed, firms differentiate themselves in other ways in order to get a competitive advantage. In the market for durable medical equipment, non-price competition

takes the form of competing based on service, a clear benefit for consumers. For example, many DME firms provide 24-hour, seven-day-a-week service to attract customers. This is similar to the competition that occurred in the airline industry under regulation. Prices could not be the focus of competition, so airlines used "white glove service" to attract customers. After the industry was deregulated, prices fell dramatically. However, as everyone knows, service has eroded in an equally dramatic manner.

The difference between the airlines and the market for medical supplies is price. When competitive bidding eliminates competition in the market for DME, service will erode – but price will not be reduced.[22] In the airline industry, competition keeps prices low and the price competition offsets the service declines. Service may be sacrificed, but at least prices stay down.

In a market where competitors are kept out, not only will service fall, but prices will rise. An example of this is cable television. In the market for cable television (generally a competitively bid monopoly or oligopoly), prices continued to rise even though service was poor: customers were often forced to wait for repairs and other on-site services during the hours of 8 am and 4 pm. Once satellite television became viable, wait times dropped.[23] When DME franchises are awarded on the basis of competitive bidding, Medicare beneficiaries can expect substantial diminution in the quality of services provided to them by the few remaining DME suppliers.

When competitive bidding for franchises enters the picture, the incentive to provide service changes significantly. Firms seeking to ensure a successful bid will fix their bid relative to the consumer surplus that they can capture and the current costs that they can avoid. Thus, in

[22] As discussed above, there may be a short term reduction in price as firms bid for franchises – but that reduction will be followed by a permanent price increase related to the market power awarded to successful bidders.
[23] Prices have not dropped appreciably, however. Successful cable franchise bidders have followed a strategy of providing basic service providing relatively poor coverage for what looks like a low price coupled with service that most consumers want at a relatively high price. In truth, the real price of cable continues to rise.

order to justify the franchise fee (the amount of price reduction in the successful bid), they plan to raise prices in the future and to cut costs – usually by reducing service.

Moreover, the economic literature contains a number of descriptions of "the winner's curse." Often the successful bidder will have the low bid because it has made mistakes in estimating its future costs at the time of bidding. In this case the firm that has won the bid has offered to sell the product at an inordinately low price, perhaps lower than it can afford. Thus, the firm must cut costs even below those that it estimated. The most likely target for cost reductions is customer service. This is made even easier by the lack of competition. Consumers have few alternatives so poor service becomes commonplace.

In short, the service provided to Medicare beneficiaries will probably fall victim to the proposed DME competitive bidding scheme – as will future prices paid by CMS and the public.

4. LARGE DME FIRMS MAY WELL "CAPTURE" THEIR REGULATORS

Capture theory suggest that when developing regulations, regulators naturally seek out those with expertise in the industry. Once these individuals have finished developing the rules, they are often hired by the firms now under the auspices of the regulations they helped craft. Indeed, there may be an expectation as they develop regulations that they will ultimately be hired by regulated firms due to their expertise. This theory, developed by George Stigler (1971), predicts that regulated firms will have greater profits than unregulated firms (and their customers will, as a result, be worse off). This is supported primarily by the reduction in competition that the regulated firms face. The downside of this for the market is that "captured" industries have

little or no incentive to control costs, or innovate. Instead, they expend their profits to artificially maintain their protected status – by fighting off competition.[24]

The literature shows significant support for Stigler's theory. Heinemann and Schuler (2004) address the propensity of financial institutions to be captured. Kalt (1994) identifies a situation in the lumber industry where, when trade duties prevail, capture has occurred, even when there is little empirical support for such an anti-trade position.

Textbooks also provide numerous examples of the occurrence of capture. We might expect that the market for textbooks would be competitive since there are numerous, qualified educators and production costs are no longer high. Despite this, textbook production and sale is an oligopoly and firms spend billions to maintain their protected position.

In many instances a regulated person helps write the regulations. For instance, lawyers must earn a law degree to practice. Since lawyers comprise the bar and grade bar exams, they can effectively limit entry and maintain a limited supply of competitors (Carton and Perloff). Additional support is provided by Spiller (1990) who shows that 49% of patronage appointee regulators went to work in the private sector in related fields after working in government. Peltzman (1976) concludes that capture is likely to occur to benefit well-organized groups with a strong incentive to seek the protection of regulators. This is accomplished at the expense of less-organized groups, typically consumers.

Will those who work in CMS, who put together the competitive bidding scheme, ultimately find employment with the limited number of firms who are allowed to supply DME after the demise of competition? If history is any guide, they will. When they get there, what will they find? Not competition that is in the public interest. Instead, they will discover an

[24] Indeed, the concentration discussion in the preceding section suggests that the proposed competitive bidding scheme may be more easily explained by capture than by any desire to reduce costs.

industry characterized by insider knowledge and networks, high levels of profits, and substantial executive compensation.

5. WHY DME?

According to national health expenditure figures provided by CMS, in 2005, the latest year for which statistics are available, total US health care spending was almost $2 trillion ($2000 billion), $1.9 trillion for health services and supplies. The makeup of this spending was as follows:

- $611 billion for hospital care
- $421 billion for physician services
- $201 billion for prescription drugs
- $143 billion for administrative costs and net cost of private health insurance
- $121 billion for nursing home care
- $86 billion for dental services
- $57 billion for other personal health care
- $55 billion for other professional services
- $47 billion for home health care
- $34 billion for non-durable medical products
- $24 billion for durable medical equipment

Only 1.3% of this spending went for durable medical equipment and another 1.8% for non-durable medical products. By contrast, 33% went to hospital care, 23% to physician care, and 11% to prescription drugs. Moreover, over the past five years the annual average spending increase was 12% for health insurance administrative costs, 11% for prescription drugs, 9% for home health care, 8% for hospital care, and 8% for physician care. Durable medical equipment spending increases averaged 4.4% during the past five years and other non-durable medical product spending increased 2.5%.

Based on these figures a case could be made that spending for medical equipment and supplies in the U.S. is not a problem at all. From 2000 to 2005 the consumer price index rose

13.4%. During this time, spending for non-durable medical equipment and supplies rose 13% and durable medical equipment and supply spending rose 24%. Physician spending increased 46%, hospital spending increased 47%, other personal health care spending increased 54%, home health spending increased 56%, prescription drug spending increased 66%, and health insurance administrative costs increased 76%. The increases for health insurance administrative costs, prescription drug costs and hospital costs are particularly problematic since government-approved consolidation in these industries over the past decade has been dramatic.

All of this suggests that current DME competitive bidding proposals will have a similar impact on the medical equipment and supply industry – not to reduce costs – but to dramatically increase them.

Even if medical equipment and supply spending is somehow construed as a problem, the problem pales in comparison to other health care spending in terms of both size and price increases. The size of spending in other health care cost sectors is as much as thirty times that for durable medical equipment and twenty times that for non-durable medical equipment. Furthermore, cost increases for other sectors of health care spending are two to three times that experienced for medical equipment and supplies. All of which suggests that CMS would be better advised to concentrate on rapidly escalating costs for administration of health insurance, for hospital care, for physician care and for prescription drugs rather than exerting resources and political capital on such a small part of the health care cost equation.

6. CONCLUSION

In short, the proposed competitive bidding for medical equipment and supplies will increase concentration and will reduce competition. Medicare already regulates price and, if price is truly too high, could reduce it. This leaves us to ask, what will we gain from competitive bidding? Administrative convenience or capture, appear to be the only justifiable reasons. There may be a short-run advantage to CMS if successful bidders are willing to cut price (or pay a premium) to gain market power, and it may be easier to regulate fewer firms. However, in the long-run, the bidding scheme will have traded a competitive market for a government-mandated concentrated market. As a result, we will have traded small, short-run benefits for major, long-run problems – poor public policy indeed.

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HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION
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February 19, 2009

The Honorable Heath Shuler
Chairman, Rural and Urban Entrepreneurship Subcommittee
U.S. House of Representatives
512 Cannon House Office Building
Washington, D.C. 20515

Dear Chairman Shuler:

Thank you for holding the Rural and Urban Entrepreneurship Subcommittee hearing on February 11 regarding Medicare's competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). On behalf of the Health Industry Distributors Association (HIDA), and our 200 member companies who are impacted by the Centers for Medicare and Medicaid Services (CMS) competitive bidding program, we submit the following comments for your consideration and the record.

HIDA is a nonprofit trade association whose members are committed to promoting safety and savings throughout the healthcare supply chain. Our members distribute a wide range of medical-surgical supplies and equipment to a diverse range of healthcare settings, from physicians' offices and hospitals, to nursing homes and home health agencies. Competitive bidding is poised to change a basic premise of Medicare: beneficiaries having access to "any willing provider," to a government driven selection process that over time will significantly reduce the number of suppliers and providers to which Medicare beneficiaries have access.

With the recent issuance of the competitive bidding interim final regulation CMS-1561-IFC, CMS has taken the first steps to restart the significantly flawed competitive bidding process. The last-minute rule, which was published in haste during the final hours of the Bush Administration, is set to go into effect on April 18 and retains *many of the same provisions as the previous rule.* Unfortunately, CMS failed to address the numerous programmatic flaws that arose during initial implementation, many of which were the impetus for the delay provisions within the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Under the provisions that remain, only suppliers that win bids in competitive bidding areas will be allowed to bill Medicare.

Moving to a national competitive bidding program raises many serious questions relating to cost, access, beneficiary protections, and fairness. The implementation of a competitive bidding program will have a significant impact on suppliers of a wide range of nursing home, homecare, and extended care products. Approximately 80% of durable medical equipment (DME) suppliers are small businesses that may be ill-equipped to participate in the federal contracting process. If a significant number of suppliers are eliminated, market competition will diminish, prices will increase, quality will erode, and patient choice will be limited. Competitive bidding unduly impacts small suppliers and negatively impacts beneficiaries in the following areas:

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- The current competitive bidding process bars suppliers who did not place a winning bid from providing DME at the winning bid price. This will exclude thousands of DME suppliers from participating in Medicare, even if they agree to the new payment rates
- Small DME suppliers normally serve relatively small territories. They are unlikely to serve an entire MSA. Mandating such extensive coverage serves as a barrier to entry
- Requires companies to bid on items and services even if these are not items or provider settings that the supplier has any experience servicing. This will lead to in a decline in the quality of provider and patient care
- Bid awards may force beneficiaries to deal with different companies for each medical need rather than dealing with one central, cost effective provider
- A reduction in the number of suppliers means *less* market-based competition and reduced access. This will almost certainly amount to a reduction in quality of care

Small suppliers allow a diverse range of health care providers to offer essential care, including oxygen therapy, respiratory assist devices, and enteral nutrition, to many of the frailest and sickest Medicare patients. In an already severely depressed economy, the implementation of a flawed competitive bidding program would lead to the loss of thousands of jobs, as many smaller suppliers would be forced out of business altogether. This is not a hypothetical scenario - only 325 out of 1,000 qualified bidders were offered contracts in the bidding areas selected for Round 1 of the program's initial rollout.

HIDA supports competition and efficiency in healthcare. **The DME industry absorbed a 9.5 percent reimbursement cut on January 1, 2009. As such, CMS is already realizing the savings they claimed would be gained through the competitive bidding program.** Budget savings aside, Medicare's "competitive bidding" system is anything but competitive. It empowers the federal government to choose "winners and losers", reducing competition, limiting patient and provider access to critical healthcare products, and adding layers of bureaucracy and cost to the system.

HIDA appreciates the Subcommittee's proactive approach. **Therefore, we ask Congress to repeal the statutory provisions within the Medicare Modernization Act of 2003 that mandate the establishment of a competitive bidding program for DMEPOS.**

Thank you for considering our comments. We look forward to working with Congress and CMS on this critical issue.

Sincerely,



Matthew J. Rowan
President and CEO



Testimony for the Record

By Esta Willman, Owner

Before the
House Small Business Sub-Committee
On Rural and Urban Entrepreneurship
Hearing Held On February 11, 2009

Chairman Shuler, Ranking Member Luetkemeyer, members of the Committee, as you consider the impact on small businesses of the Centers for Medicare and Medicaid Services (CMS) program for Competitive Acquisition of Durable Medical Equipment and Other Items (National Competitive Bidding Program or CBP), please accept these comments as my testimony for the record regarding this subject. Please note that a narrative of my personal involvement in the competitive bidding process for my business follows in supplement to the main testimonial document.

I will never forget the day in late March of last year when the letter from CMS arrived informing me that my business was not awarded a contract in any of the product categories in which we bid. The realization that without some intervention, my business would be closing its doors hit me like a slap and sent me to the floor. All my family had worked for over the years, all that we had hoped our hard work would yield, all of the people we had taken care of over the years, all of it to be taken away because I didn't bid low enough. . .

The Competitive Bidding Program will be detrimental to small businesses in the durable medical equipment industry:

- Small suppliers not awarded contracts will be at extreme risk of business failure from loss of a significant revenue source
- Small suppliers awarded contracts will be at increased risk of business failure due to:
    - Drastically reduced reimbursement rates
    - Difficulties with required territory coverage
    - Difficulties with required product mix coverage
    - Increased stress on limited resources needed to
        - Implement operations to provide contracted products and services
        - Administer any necessary subcontract relationships
        - Acquire market share to offset loss of revenue due to lower reimbursement

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Background

I am writing from my perspective as an owner of Medi-Source Equipment & Supply, a durable medical equipment (DME) supplier located in Yucca Valley, California. Medi-Source sells, rents and services most types of general DME, oxygen and other respiratory equipment, standard and complex power wheelchairs and supplies.

Our family-owned business is considered a small supplier as defined by the CBP and a small business as defined by the Small Business Administration. We serve patients in areas designated as rural by the Office of Rural Health Policy, and yet, approximately fifty percent of our service area and patient population were included in the Riverside/San Bernardino Competitive Bid Area (CBA) in Round 1 of the CBP. We are accredited and participated in the Round 1 bidding process.

Concerns for Small Businesses under the CBP

General Concerns

Like my business, the great majority of DME suppliers are considered small businesses. Like Medi-Source, generally each DME supplier serves patients in local communities immediately surrounding their location. Historically, because most items of DME are similar from one brand to the next and because most payment for DME (pricing) is set by outside agencies (such as Medicare, Medicaid and private insurers), small DME suppliers have competed largely on the basis of quality of service.

There is a real, valuable service component to the provision of DME items. This service component is recognized through the various requirements that DME suppliers must adhere to such as mandatory accreditation under the Medicare program. If implemented as planned, the Competitive Bidding Program would have eliminated the traditional, service-driven, competitive influences in the market. Suppliers would have been awarded contracts based upon the lowest bid with no meaningful service-related consideration. Those without a winning contract would have been prohibited from providing the competitively bid items to Medicare beneficiaries in the CBA except under certain, limited circumstances.

For my company, as well as for many small DME businesses, Medicare is the largest payer of DME items. This makes sense considering the need for DME items is generally a result of conditions affecting our elderly or disabled citizens. To eliminate Medicare from the payer mix for these small DME businesses would have meant likely closure and/or bankruptcy. Hence, the Competitive Bidding Program ultimately would have served to eliminate many small suppliers in the CBA's who were not awarded a contract by taking away their ability to continue serving a significant portion of their patient population. These small suppliers would be unable to remain in the market place and compete on

traditional grounds, and, thus, the CBP would have ultimately served to reduce market competition as those suppliers were forced from business.

Concerns Related to Preparation and Submission of the Request for Bid

The process for completing and submitting the Request for Bid (RFB) was a confusing, time consuming and inefficient process due in large part to CBIC system-wide inefficiencies, miscommunications and technological malfunctions. The unnecessary consumption of resources, when combined with the necessary consumption and temporary reallocation of resources (personnel time, technology and funds) needed to research all of the various elements of the RFB and prepare and submit the RFB package was difficult and costly for us as a small supplier. As a small business, we don't have a vast array of resources upon which to draw. Our small business has only five full time employees. The RFB required a significant and costly redistribution of work over a significant period of time.

Concerns Related to Bid/Contract Requirements

In Round 1, there were various requirements to which a supplier had to agree in order to submit a bid and receive a contract. Some of these requirements were problematic for a small business.

Serving the Entire CBA

One of the requirements was that the supplier had to agree that, if it was awarded a contract, it would service the entire CBA. The Riverside/San Bernardino CBA, as defined in Round One for non-mail order items, covered a geographic area of approximately 6,250 square miles. Many of the areas included are in mountain or outlying communities, separated from urban centers by significant distances and/or geographic barriers. In demonstration of the Riverside CBA's size consider that the distance from the community of Barstow in the north to Murrieta in the south is approximately 120 miles. Depending on traffic conditions, it would take a DME delivery technician a minimum of two hours to travel in one direction to deliver a covered item; an item potentially as inexpensive as a walker.

With limited employees and other resources it would have been impossible for my small business to service that large of a geographic area without a significant acquisition of new resources at considerable cost. Yet, to not agree to serve the entire CBA was not an option. If we were to bid and ultimately accept a contract, serving the entire 6250 square mile area was required.

Providing the Entire Product Mix in a Product Category

To submit a bid, the supplier had to agree that, if it was awarded a contract, it would provide the entire product mix detailed in the product category bid. While for some categories, this was most likely not problematic, for some it was very much so. For example our company does not currently supply the

liquid oxygen modality included in the Oxygen Category. To add this modality to our product mix would be cost prohibitive. Liquid oxygen is not a simply "a piece of equipment"; it is a hazardous, cryogenic substance requiring special handling. There would be significant costs to our business to prepare for the first delivery of this type of system: development of needed infrastructure; development of operational and safety procedures; employee training; arrangements to meet the special handling and transportation requirements for the liquid oxygen; necessary equipment acquisition. We would have been required to add this modality to our product line in the event that we received a *single* request for liquid oxygen; for to not provide an item as requested would have been a breach of the CBP contract. We tried to arrange for a subcontractor to handle this in the event we were awarded a contract, but those companies we contacted were unwilling to commit to serving the entire geographic region of the CBA. The point being, that some of the product categories contained specialty type items that not all small businesses are prepared to handle nor which they can afford to become prepared to handle.

Concerns with Subcontracting – Not a Sustainable Solution for Small Businesses

Subcontracting was espoused as a means for small supplier businesses to cover the large geographic region of a CBA and/or the increased/diverse product mix of a product category. This was explained to me to be a way that a small supplier could comply with contract provisions if it could not serve the entire CBA/product mix. In reality, in my business' case as a losing bidder, subcontracting turned out to be extremely difficult to arrange or afford and ultimately we were unable to finalize agreements with willing contract suppliers up to the time of the MIPPA delay.

Lack of Subcontracting Guidelines from CMS

The contract suppliers with whom I tried to arrange subcontract agreements were stymied in subcontract preparations in some part because the requirements of a subcontract were not clear. Up to the first round MIPPA delay, there were no definitive guidelines from CMS outlining permissible provisions for subcontract relationships. To my knowledge (and the knowledge of the industry respected attorneys I retained at the time) questions such as whether or not the contract supplier had to own the rental inventory placed under a subcontract agreement were not definitively answered. At a minimum, clear subcontracting guidelines should have been provided with the RFB so that bidding entities could include costs associated with subcontracting in their bid calculations if that is the means by which they intended to fulfill contractual obligations. Small businesses were placed at a disadvantage in their ability to bid effectively and once awarded a contract to meet the contractual demands.

Subcontracting Unfairly Adds Costs to Small Businesses

Even if guidelines had been issued by CMS, I believe that the additional layer of administrative burden created with a subcontract relationship and its resulting costs places the small supplier that is reliant on

such relationships at a distinct disadvantage to its larger competitor not so reliant. Small businesses that would need to rely on subcontracting to be able to fulfill the contract terms would incur a cost not incurred by those organizations with a larger regional presence.

After a careful analysis of the single payment amounts that were established in the Riverside CBA, I found the margins to be so small in many cases that to appropriately compensate a subcontractor for their services would have left little, nothing, and even in some cases a deficit of funding to cover the contract supplier's related costs. On the opposite side, I found contract suppliers suggesting payments to me as a subcontractor that were roughly half of the reimbursement level I currently receive for these items. In either case, it would have been extremely difficult to remain a viable business as a small contract supplier or a subcontract supplier.

CBP Moves Focus Away from the Patient

There were many suppliers, such as myself, who bid using acquisition and service provision cost data that would allow us to be able to continue to operate our businesses successfully while providing the service and quality to patients that has made us competitive and successful in the current market. Other suppliers bid with the philosophy and intention of taking an administrative percentage from the reimbursement for items and subcontracting the actual patient provision of those items to other suppliers.

I was contacted by several contract winners looking to subcontract: some had never before provided the types of items for which they had been awarded a contract; others did not have a physical presence in the CBA. All wanted our company to provide the same items and the same services we were accustomed to providing to the same communities we have served for a fraction of what we had been traditionally reimbursed. In some cases the proposed subcontract rate represented a 50% or greater reduction to the then current rates. Had CBP not been delayed, the contract suppliers intending to use this type of business model, the "lowest bidders", would simply have been taking the small "losing" suppliers' margins simply because they were the lowest bidder, not because they would actually be providing competitive quality and service.

Post Contract Award Concerns for Small Businesses

It is worth stating again, that the small supplier who bid and wasn't awarded a contract was in severe jeopardy of being forced out of business. We bid in five product categories. Some of these categories represent a significant percentage of our revenue. Even if we had received a contract in one of the less significant categories, the lack of a contract in one of the more significant categories would have been devastating to our company.

Cost of Administering the Contract

It is not only those small businesses not awarded contracts that suffer under competitive bidding. Small businesses that were awarded contracts had their own difficulties.

I spoke with several small suppliers while trying to arrange subcontracts for my business. Some were small businesses in which the business owner was working directly in the daily operations of their business and was ill equipped, from a resource standpoint, to implement the operational changes needed to effectuate the contract and maintain their business' viability. Some were scrambling to figure out how they were going to comply with contract provisions. Others simply gave up and had no plans to actually serve the entire product mix or geographic area, despite being contractually obligated. The day prior to the implementation date of July 1, I contacted every oxygen contract "winner" to assess each business' level of readiness to accept referrals in our area; fully 75% were not ready and had no anticipated time frame in which they would be ready to deliver oxygen to our area's patients. It became apparent to me that the "winners" of contracts might just end up being "losers" in the long run because the cost in administering the contract ran the risk of overextending their resources.

Rate Reductions vs. Increased Market Share

One of the "premises" of the CBP is that while the payment rates for products are reduced through the CBP, suppliers would be able to "make up" those lost revenues through increased market share. This increased market share is not automatic. In reality, to obtain a significantly increased market share there has to be some level of a marketing plan or marketing activity that brings additional referrals to the business. Again small businesses were at a disadvantage to their larger contract-awarded competitors. These small suppliers lacked in areas such as manpower, marketing expertise and funding to be able to "compete" with the larger contract suppliers in acquiring additional market share.

Concerns with Non-Bidding Small Suppliers

Many suppliers did not submit a bid. From conversations I have had there were a variety of reasons for this: they did not understand how to do it – it was a complex process made even more difficult by systematic poor performance and inefficiencies with the CBIC; many did not bid because they felt the bid levels ultimately required to be one of the few awarded a contract would be too low to remain in business; many felt that they could not realistically provide the full array of required items and services to the full geographic area as required by the CBP. Like my business, for many of these small suppliers, Medicare beneficiaries make up the greatest percentage of their business. Without Medicare it is doubtful our businesses would survive. It is disturbing to me that some small suppliers were willing to give up the fight to save their businesses. Because I feel it too, I believe it speaks to their diminished will to continue to try to build a business under the unrelenting regulatory, administrative and financial

burdens being imposed upon our industry. They are simply tired of their good efforts toward building their small business being constantly undermined by forces beyond their control.

Conclusion

When my family went into business it was with the "American Dream" in mind: If we used our ingenuity, worked hard, ran a good ship and played by the rules, we could build something for our family's future. Never did we imagine that we would simply be cut out of the picture without the opportunity to compete on a level playing field under reasonable requirements for all involved. As a small business owner, I am concerned for my business' future under the Competitive Bidding Program. I worry that we will have to layoff employees; that we will have to cut services to our patients some of whom we've been serving for decades; that we will have to close our doors.

The concept of reducing Medicare expenditures is good – the manner in which it is being accomplished with competitive bidding is not good, and in some cases may do damage to the frailest in our community by restricting access to needed items and services by eliminating small local suppliers. I believe a means to reduce Medicare spending for DMEPOS can be developed without compromising quality or access to services and products for those we ultimately serve, the Medicare beneficiary.

I urge a repeal of the Competitive Bidding Program and the development of a cost savings approach that allows small suppliers to continue serving their patients and remain in business.

Thank you for consideration of my testimony.

Sincerely,



Esta E. Willman, Owner

Testimonial Supplement

Direct Experience, Competitive Bidding Round 1

I personally performed or directly supervised all aspects of our company's bid preparation and submission in Round 1 including:

- Review of CBP preliminary documents, the Final Rule and ongoing, periodic communications from CMS and the Competitive Bidding Implementation Contractor (CBIC);
- Attendance at industry and PAOC events;
- Compilation and analysis of acquisition cost, company operational and financial data to determine bid limitations and amounts within an acceptable business model;
- Development of bid calculators and spreadsheets for data manipulation and analysis;
- Consideration of multiple business service plans assuming a variety of down-line conditions;
- Obtaining bidder and user identification numbers and access to the CMS Competitive Bid Submission System (CBSS) from the CBIC;
- Preparation and submission of all required bid package documentation and information; completion of the bid submission process through the CBSS and with CBIC.

During the bid submission process, I had first-hand experience with both the policies and processes that were implemented smoothly, without difficulty and without contention, as well as those that did not go smoothly, were mildly to extremely difficult and with contention of varying degrees.

Medi-Source was not awarded a contract in any of the five categories in which we bid in Round 1. Having considered that eventuality, our business plan was to try to become a subcontractor for organizations that received a contract in those areas. During the process of preparing to subcontract and in spite of a lack of guidance from CMS on permitted subcontracting provisions, I:

- Attempted to develop a subcontractor/contractor operational model;
- Worked with industry-recognized legal council in developing a potential subcontract agreement template;
- Entered into discussions and negotiations with several contract winners and industry consultants.

Despite my best efforts and despite the expressed desire of several contract winners to enter into subcontracting agreements, we were not successful in executing any subcontracting agreements, both for lack of profitability and lack of certainty in the operational provisions required.

Additionally, I had discussions with contract winners and consultants on issues not related to subcontracting, but instead, related to direct implementation of services under their contract.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement of:

National Association of Chain Drug Stores

On:

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

To:

U.S. House of Representatives
The House Committee on Small Business
Subcommittee on Rural Development, Entrepreneurship and Trade

February 11, 2009

National Association of Chain Drug Stores (NACDS)
413 North Lee Street
Alexandria, VA 22314
703-549-3001
www.nacds.org

INTRODUCTION

Thank you for this opportunity for the National Association of Chain Drug Stores (NACDS) to submit a statement on the impact of the competitive bidding program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) on Medicare beneficiaries and pharmacies. NACDS represents approximately 170 companies operating retail pharmacies in virtually every community in the country. NACDS represents national companies with thousands of retail pharmacies as well as local chains that operate as few as four pharmacies. Regardless of their size, all NACDS members are very concerned about the competitive bidding program and the negative impact it will have on Medicare beneficiaries' health.

As the most readily accessible healthcare providers, pharmacists are in a unique position to assist Medicare beneficiaries with their DMEPOS needs and to assess outcomes related to their use. Many Medicare beneficiaries obtain their DMEPOS, particularly diabetic supplies, from their local pharmacy. In fact, a recent study conducted by HealthPolicy R&D found that nearly two-thirds of older diabetic patients obtain their diabetic test strips from retail-based community pharmacies.[1]

In addition to furnishing DMEPOS supplies, one-on-one patient consultations provided by local pharmacists are often the first opportunity to identify chronic illnesses and changes in patients' conditions, and these consultations often result in early detection, referral, and treatment. In addition to helping to preserve the patient's health, early detection and treatment provide tremendous savings for the Medicare program. Continued participation of community retail pharmacies in serving Medicare patients should therefore be a priority of the Medicare program.

RECOMMENDATIONS TO ENSURE BENEFICIARY ACCESS TO HIGH QUALITY PRODUCTS AND SERVICES IN THE MEDICARE DMEPOS PROGRAM

We raise the following concerns and offer our recommendations to help the Committee ensure that Medicare beneficiaries continue to have access to high quality products and services from their pharmacies. First, expansion of the competitive bidding program to include diabetic supplies sold at retail pharmacies or CMS' plan to include diabetic supplies in the national mail-order program could limit participation by pharmacies and reduce diabetic patients' access to life-saving supplies and services. Second, as CMS moves forward with the first round of competitive bidding, it is critical that contract suppliers' marketing practices be subject to strict oversight by CMS, and any communication to diabetic patients contain information about the continued availability of diabetic supplies at retail pharmacies. Third, we urge Congress to consider the competitive bidding program within the context of a broader set of difficulties pharmacies and patients face in the DMEPOS program. CMS' recent initiatives, such as the requirement for pharmacies to obtain accreditation and a surety bond in the amount of

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[1] HealthPolicy R&D, *Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community-Based Retail Pharmacies and Blood Glucose Monitoring,* Washington, DC, January 2006.

$50,000 per location create significant administrative and financial burdens for pharmacies, resulting in the likelihood of beneficiary access difficulties.

Congress should not allow CMS to expand the competitive bidding program to include diabetic supplies sold at retail pharmacies, or to move forward with a national mail-order program for diabetic supplies.

In making several positive changes to the competitive bidding program, the Medicare Improvements for Patients and Providers Act (MIPPA) recognized that diabetes testing supplies are unique products that require careful consideration in competitive bidding. As a result, MIPPA specifically excluded diabetes testing supplies sold at retail from the new round of competitive bidding. Nonetheless, in the recent interim final rule, which was issued by the previous administration, CMS notes that it is considering alternatives for the competition of diabetic supplies after Round One re-bid.[2] Ostensibly, this could mean expansion of competitive bidding to retail diabetic supplies, or inclusion of diabetic supplies in the national mail-order program. Under either scenario, Medicare beneficiaries' health and the fiscal well-being of the Medicare program are in danger.

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 to manage their diabetes from the same pharmacy. As mentioned earlier, the majority of older diabetic patients rely on their retail pharmacies for their diabetic supplies. Evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for diabetic patients. Through programs such as the "Asheville Project," the pharmacy setting has been shown to provide a successful platform for initiatives to improve adherence to testing and treatment regimens for patients with diabetes.[3] Other private and public 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 disrupt these pharmacist-patient relationships while further experience is being gained in the effectiveness of community-based pharmacies in promoting adherence to diabetes treatment and monitoring regimen.

Unlike other DME products, CMS did not evaluate the effects of competitive bidding of diabetic supplies during the competitive bidding demonstration projects. Thus, expansion of the competitive bidding program to diabetic supplies sold at retail pharmacies will be a blind implementation of an unproven policy. Similarly, the plan to expand the mail-order program for diabetic supplies would not be supported by any evidence that the program would ensure quality products and services or guarantees as to patients' access to life-saving diabetes testing supplies. To the contrary, it is quite likely that a winning mail-order supplier may limit access to high quality products and eliminate patients' choice in

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[2] Changes to the Competitive Acquisition of DMEPOS by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008, 74 Fed. Reg. 2873, 2878 (January 16, 2009).

[3] Pharmacy Times, *The Ashville Project: A Special Report* (October, 1998), *available at* http://www.pharmacytimes.com/files/articlefiles/TheAshevilleProject.pdf (last accessed February 11, 2009).

their diabetes care in order to cover reduced reimbursement under the mail-order program. CMS has not engaged in any evaluation of the impact of a mail-order program for diabetic supplies on patients' health or increased costs to the Medicare program from missed or inappropriate testing of blood glucose. At a time when Medicare is attempting to move away from fragmented care, both proposals will interfere with patient access and would undermine years of progress made in diabetes management.

Further, a study conducted by HealthPolicy R&D examined issues related to competitive bidding of diabetic products and associated services and noted the following:

- Costs to the Medicare program will increase if access to the full range of monitoring options is lost or if the frequent in-person counseling by retail pharmacists is disrupted.
- The complexity of using glucose monitors, particularly for an elderly beneficiary, is a major concern. Pharmacists play an important role in helping beneficiaries select the optimal monitors and in the correct use of such monitors, both in terms of initial instruction and subsequent reinforcement of that instruction over time. Much of the professional support originates from the ongoing relationship between beneficiaries and pharmacists.
- CMS excluded blood glucose monitors and supplies from the DME competitive bidding demonstration project, due, in part, to concerns regarding the complexity of matching glucose monitors with the appropriate testing supplies.
- The competitive bidding program could operate contrary to Medicare's current and future initiatives that are designed to promote adherence to blood glucose regimens and reduce overall costs in managing diabetes.

We urge Congress to ensure that CMS does not implement programs that limit patients' access to community pharmacies. The presence of licensed pharmacists at community pharmacies gives patients the opportunity to discuss optimal glucose monitors for their needs and the proper matching of test strips to these glucose test monitors. This individualized attention is critical in ensuring patient compliance with therapy regimen and improving health outcomes for diabetic patients. The benefits 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.

CMS should maintain greater oversight of marketing by contract suppliers and ensure balanced statements to beneficiaries about continued availability of diabetic supplies at retail pharmacies.

We are very concerned that beneficiaries in and outside of the competitive bidding areas may mistakenly believe that they are required to utilize mail-order pharmacies to obtain their diabetic products and services. During the previous round of competitive bidding, CMS' lack of oversight of marketing practices allowed many mail-order suppliers to engage in potentially misleading advertisement campaigns. Confusion caused by the suppliers' advertisements were compounded by statements related to competitive bidding

included in beneficiaries' explanation of benefits (EOBs) documents sent by CMS to beneficiaries outside the 10 metropolitan statistical areas (MSAs).

Without appropriate oversight of contract suppliers and balanced statements from CMS and contract suppliers, diabetic patients in and out of competitive bidding areas may be confused about where they can obtain their testing supplies, causing many patients to depart from their doctor's orders. Therefore, CMS should ensure that every communication sent to diabetic patients includes a statement about the continued availability of diabetic supplies at retail pharmacies. In addition, Congress should require CMS to work with pharmacists and other healthcare providers in developing proper communication materials to ensure that patients are not steered away from retail pharmacies, depriving them of professional counseling by their pharmacists.

State-licensed pharmacies should be exempt from the requirements to be accredited and to obtain a $50,000 surety bond to participate in Medicare.

In addition to the competitive bidding program, we urge Congress to consider other CMS initiatives related to DMEPOS that are likely to create disruptions in patient care. In particular, the requirement for pharmacies to obtain accreditation and a $50,000 surety bond for each enrolled practice location will render many pharmacies unable to participate in the Medicare program, thereby forcing patients to forego critical healthcare items and services.

The Medicare Modernization Act (MMA) requires DMEPOS suppliers to be accredited to sell covered items to Medicare patients. In addition, the Bush Administration issued a final regulation requiring DMEPOS suppliers to obtain a $50,000 surety bond for each enrolled location that serves Medicare beneficiaries. Both of these rules were issued to combat fraud and abuse and to ensure that only quality suppliers participate in the Medicare program. While we agree with the need to eliminate fraud and abuse from the Medicare program, we do not believe that requiring accreditation or a surety bond from state-licensed pharmacies will accomplish this goal. CMS has at its disposal a variety of tools to ensure provider integrity in the Medicare program, which CMS could pursue instead of these onerous requirements.

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 review to ensure that their operations are compliant with federal and state laws. Further, state pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with appropriate laws and regulation. Today's pharmacists are highly educated, licensed experts in the use of medications and medical devices who advise patients and healthcare providers. Pharmacists are ideally situated to provide Medicare patients using diabetic supplies and other DME items with appropriate counseling and information on the proper use of these items. These qualifications clearly distinguish pharmacies and pharmacists from other unlicensed and unregulated suppliers. Therefore, requiring accreditation or a surety bond from licensed pharmacies and pharmacists is unnecessary.

Although CMS used its discretion in exempting several providers from these requirements, it did not exempt state-licensed pharmacies and pharmacists despite receiving several comments in support of such an exemption. CMS' justification that their exemption is not supported by congressional intent lacks merit. Congress intended accreditation and surety bond to be targeted toward suppliers that pose serious risk to the Medicare program, and not legitimate healthcare providers. This principle is implicit in the authority granted to CMS to exempt providers. Unlike unscrupulous suppliers for whom these rules were intended, pharmacies and pharmacists are state-licensed healthcare providers who are subject to disciplinary actions from their state boards of pharmacy for engaging in fraudulent behavior, in addition to prosecutions by state and federal authorities. In this regard, they are no different than physicians, non-physician practitioners, and others who received exemptions from these requirements.

The impact of these requirements is not limited to Medicare. Several state Medicaid programs require DMEPOS suppliers to be enrolled in Medicare in order to provide DMEPOS to Medicaid patients. If pharmacies in these states are unable to afford the cost of accreditation or the surety bond, they will be forced to turn away Medicaid patients in addition to Medicare beneficiaries. Congress did not envision the consequences of anti-fraud efforts to impede the access of vulnerable populations to needed healthcare.

In addition, pharmacies have a tremendous positive impact on their local economy, which could be eroded by CMS' DMEPOS initiatives. The requirement for accreditation and surety bond for state-licensed pharmacies stands in the way of pharmacies serving their patients and creates unnecessary economic and administrative strain on their operations. As Congress seeks to stimulate the economy, these unjustifiable costs will make it exceedingly difficult for pharmacies to expand business, hire more staff or continue providing services to patients.

We applaud Representatives Marion Berry (D-AR) and Jerry Moran (R-KS) for introducing legislation (H.R. 616), which would exempt pharmacy suppliers from the accreditation requirements by including pharmacists and pharmacies in the list of healthcare providers that CMS has already exempted from meeting the quality standards for DMEPOS accreditation until specifically designed quality standards are developed. Hence, we urge Members of the Committee and Congress to support legislation that would exempt state-licensed pharmacies and pharmacists from onerous and unnecessary accreditation and surety bond requirements.

CONCLUSION

NACDS appreciates the opportunity to work with Congress to ensure that our nation's seniors have access to the best healthcare products and services. We thank the Committee again for the opportunity to present our views.

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STATEMENT OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION FOR THE RECORD OF HOUSE SMALL BUSINESS COMMITTEE'S SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP'S OVERSIGHT HEARING ON SMALL SUPPLIERS AND THE DMEPOS COMPETITIVE BIDDING PROGRAM

FEBRUARY 11, 2009

Chairman Shuler, ranking member Luetkemeyer, and members of the subcommittee and the committee, thank you for holding this oversight hearing regarding the serious barriers that small suppliers will face in trying to continue to provide Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and services if competitive bidding is implemented. As community pharmacies hold one out of every three DME supplier numbers, and many of these are utilized by independent community pharmacists at small pharmacies serving rural and inner city communities, the inability of these pharmacies and pharmacists to provide their patients with continued access to DMEPOS under competitive bidding is a problem that this subcommittee, the full committee and Congress should address before proceeding with implementing competitive bidding.

NCPA represents the nation's independent community pharmacists, including the owners of more than 23,000 pharmacies, with nearly 60,000 pharmacists, over 300,000 employees and the millions of patients who rely on us for their prescription care.

Community pharmacists provide vital prescription services in rural, inner-city and urban areas, including services offered almost exclusively by independents, such as compounding, medication therapy management, and home delivery. DMEPOS and related services are especially vital areas of care and consultation provide by independents.

Because of the face-to-face relationship with their local independent community pharmacist, our patients are more likely to: take their medicines on-time; take them properly; refill meds before they run out; and avoid harmful drug interactions. Patient access to their trusted independent community pharmacist helps to lower health care costs by promoting patient health every day. Through this attentive patient care and dedication to their communities, pharmacies are able to compete with chains and mass merchants. This access is crucial, as forcing beneficiaries to lose that access to their local pharmacies to turn to mail order will not only cost more in the long run, but it will also lead to reduced quality of health care and health outcomes.

Many independent community pharmacies provide diabetes and related supplies for their patients in addition to other DMEPOS and prescriptions. CMS' recent interim final rule on competitive bidding – in addition to its regulations on accreditation and the surety bond -- will prove unduly burdensome to independent community pharmacies and will cause many of them to leave the program. In the aborted first round of competitive bidding, less than two percent of the suppliers submitting bids were independent community pharmacists, despite the fact that community pharmacies hold half of the active DME supplier numbers.

The negative impact of decreasing the number of independent community pharmacies in the DMEPOS program will be most pronounced in rural areas, where independent community pharmacies are concentrated. Medicare DMEPOS beneficiaries will either: 1) have to find and drive away from their communities to other pharmacies that are able to continue participation in the DMEPOS program; or 2) resort to mail order to obtain some supplies that need custom fitting and personalized patient care, such as therapeutic shoes and braces, and compression gradient stockings. Even so-called standard items such as canes, walkers and commodes should be adjusted by the pharmacist. Also many items are best not sent by mail, such as ostomy supplies, which are heat sensitive. Finally, the transportation and access problems of urban beneficiaries must also be considered.

NCPA finds it instructive that this hearing is entitled "The Impact of Competitive Bidding on Small Businesses in the Durable Medical Equipment Community." "Community" is indeed an appropriate term, as evidenced by the testimony made by small suppliers during the October 31, 2007 House Small Business Committee's Investigations and Oversight subcommittee hearing on small suppliers and the DMEPOS competitive bidding program. The testimony by the small suppliers showed in very concrete terms the beyond-the-call-of-duty care that they gave to their clients, such as personally delivering emergency supplies and services to them, at great cost and time. In stark contrast to this quality of care, NCPA understands that some of the winning bidders in the aborted first round of competitive bidding were not only out of state suppliers, but were also companies that had never previously supplied the DMEPOS for which they won contracts. Competitive bidding certainly does have a negative impact on the DME community, to the detriment of quality care to patients.

The House Small Business Committee's Investigations and Oversight Subcommittee was told at that hearing about some of the technical problems and, to be frank, mistakes that CMS made while starting to implement the first stage of the competitive bidding program (since suspended), including twice extending the deadline to submit bids, thus causing confusion and discouraging attempts to participate in the program. NCPA highlights for you the end result of those mistakes and problems:

I. Contrary to CMS' claims, it is already clear that independent community pharmacists will not be able to provide DMEPOS to their patients:

- The high costs of unnecessary accreditation and competitive bidding have discouraged independent community pharmacists from submitting competitive bids or even trying to obtain accreditation. From the bids submitted in the first 10 Metropolitan Statistical Areas (MSAs) that CMS had identified for competitive bidding of DMEPOS, the vast majority of independents were clearly planning to only sell diabetes test supplies and other non-competitively bid DMEPOS. In addition, it was thought then that CMS would eventually subject even diabetes test supplies to competitive bidding. Indeed, in the final surety bond rule, which many groups are asking to be reviewed and delayed by 60 days, CMS announced its intention to impose mail order and subject diabetes test supplies to competitive bidding in the near future.

- There are currently 18,000 suppliers in the first 10 MSAs. Retail pharmacists hold one-third of the DMEPOS supplier numbers in the country.

- CMS thought that 16,000 of those 18,000 suppliers would submit bids and that it would award half of those. Instead, CMS announced on October 11, 2007 that only 2,200 locations had applied for accreditation as a prerequisite for submitting bids. **In the withdrawn first round of competitive bidding, less that 2 percent of the submitted bids were from independent community pharmacies, even though pharmacies hold one third of the total, and one half of the active, DME supplier numbers.**

- CMS appears all too willing to steer patients that will lose access to these supplies at their local pharmacy to mail order – which does not solve the problem of patients having multiple needs and thus now having to turn to multiple sources to address those needs, nor does that policy take into account the valuable consultation, fitting and monitoring services that independent community pharmacists provide. Indeed, in the final surety bond rule, CMS indicated that it would turn to mail order.

II. The high costs of complying with CMS DMEPOS regulations, including unnecessary accreditation and surety bond costs, shows why independent community pharmacists will not be able to provide DMEPOS, thus causing access to care problems:

- **Pharmacists must be exempted from a $50,000 surety bond requirement** (CMS-6006-P) which would cost $1,500 to obtain.
    - This requirement is burdensome and unnecessary and would not serve the intended purpose of discouraging fraudulent suppliers.
    - CMS conceded that based on the surety bond costs alone, one-fourth of DMEPOS suppliers would not even submit bids to stay in the program.

- Combined with unnecessary accreditation requirements, independent community pharmacies will have to pay at least an initial $5,000 - $6,500 simply to obtain Part B supplier numbers, with additional annual costs for training and education. **Given the small amount of DMEPOS that an average independent community supplies (an average 7% of an independent's business) and the low margin on those supplies, many independents will be forced out of the program. The winning bids in the aborted first round of competitive bidding were, on average, 26% below current fee schedule prices. NCPA is concerned about the quality of those products and services, and will simply be unable to provide their patients with them at those prices, thus negatively impacting patient access to quality health care.**

- CMS' $3.5 million small business definition (which CMS now uses even though it used a $6 million figure in last year's final rule regarding accreditation and a $6.5 million figure in the AMP final rule) further forces independent community pharmacists out of the program. In addition, the revenues of all the stores of an independent community pharmacy owner are combined to see if it exceeds the $3.5 million small business ceiling.

- The 30% target number for small bidder participation does not adequately allow suppliers to band together to submit acceptable bids, as CMS had envisioned.

- Pharmacists were the only state licensed medical professional to not receive CMS' conditional exemption from the accreditation requirement.[1] CMS made this decision despite touting that the prospect of losing its license and the "training and expertise" these professionals have were the reasons for granting the exemption to licensed medical professionals. In addition, CMS claims that pharmacists are not eligible to receive an exemption from the surety bond requirement because of a narrow interpretation that they are suppliers, and not medical providers. CMS has the authority to treat pharmacists as they are – licensed medical professionals, and we urge Congress to weigh into CMS on this issue.

- **Beneficiaries will be forced to travel to other locations for supplies which they previously obtained at their local independent community pharmacy. Ironically, CMS' DMEPOS regulations pressure Medicare patients towards mail order and the internet sources, where fraud is most prevalent.[2],[3],[4]**

III. Congress should weigh in on problems with the DMEPOS program:

Consistent with the terms of the Obama Administration's January 20, 2009 memorandum regarding treatment of regulations that have not yet reached their implementation date:

- CMS should delay implementation of and reopen for public comment the interim final competitive bidding rule.
- CMS should do the same for the final surety bond rule.
- Independent community pharmacists and those without any history of Part B billing or Part B billing problems should be exempt from the surety bond requirement. NCPA wishes to be clear that it supports rational methods of combating fraud, such as expelling fraudulent suppliers from the program in a more stringent manner than CMS has proposed to date.

Please do not hesitate to contact NCPA's Government Affairs department at (703) 683-8200 if you have any questions. We would be glad to provide you with information and to testify at the next hearing that the subcommittee or full committee might hold on this topic.

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[1] Pharmacists are not only licensed and undergo oversight by state licensing boards, they are also state licensed businesses.

[2] On the list of Excluded Individuals and Entities on the GAO website, under the broadest definition of fraud possible, at most 0.71% of all pharmacies can be said to have engaged in some kind of fraud – technical or otherwise. That statistic is overbroad, as it includes DME and other fraud, and it over counts pharmacies.

[3] A recent NCPA/NACDS study conducted by Accenture, as well as the European Alliance for Access to Safe Medicines found that unregulated online drug operators have been found to cause harm and even death in some cases. Counterfeit drugs are driven almost entirely by unlicensed, rogue Internet Web sites. Some 68% of medications purchased online are fake or sub-standard and 95.6% of Internet pharmacy sites are operating illegally." [1] European Alliance for Access to Safe Medicines, The Counterfeiting Superhighway, June 2008. The full report is available at www.eaasm.eu.

[4] Further evidence of the magnitude of the problem was demonstrated in Congressional testimony by GoDaddy.com, a leading online registrant, which revealed it has had to suspend 6,000 of these rogue sites in the first half of 2008 as a result of their practices. Testimony of Christine N. Jones, General Counsel and Corporate Secretary, Go Daddy Group Inc., Before the House Committee on the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security United States House of Representatives, June 24, 2008 hearing on Online Pharmacies And The Problem of Internet Drug Abuse.

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