MEDICARE'S COMPETITIVE BIDDING PROGRAM FOR DURABLE MEDICAL EQUIPMENT: IMPLICATIONS FOR QUALITY, COST AND ACCESS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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SUBMITTED MATERIAL

MEDICARE'S COMPETITIVE BIDDING PROGRAM FOR DURABLE MEDICAL EQUIPMENT: IMPLICATIONS FOR QUALITY, COST AND ACCESS

WEDNESDAY, SEPTEMBER 15, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:10 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Dingell, Eshoo, Green, DeGette, Barrow, Castor, Sarbanes, Sutton, Braley, Doyle, Waxman (ex officio), Shimkus, Hall, Whitfield, Pitts, Burgess, Blackburn and Gingrey.

Staff present: Tim Gronniger, Professional Staff Member; Virgil Miler, Professional Staff Member; Alvin Banks, Special Assistant; and Sean Hayes, Minority Counsel, O&I.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. I call the meeting of the Health Subcommittee to order.

Today the Health Subcommittee will examine Medicare's competitive bidding program for durable medical equipment and its implications for quality, cost and access, and I would yield myself 5 minutes initially for an opening statement.

As I think many of you know, durable medical equipment, prosthetics, orthotics and supplies—DME is the acronym—that coverage has been a longstanding issue of this subcommittee and I know it is an issue of great interest to many Members of the House of Representatives. I want to thank our witnesses for being here today, and I am told by my staff that this is one of the most popular hearings she has staffed with a witness list that was hotly sought after. Interestingly, though, I will say, Tiffany, the reason I was late is because I had a political science class from Rutgers, as you know, in my district that was in the office, and they wanted to know why with the—I don't know how they put it—with all the major issues of the day, we were having a hearing on durable medical equipment, and I explained to them that it had a lot of job implications and that we were concerned about jobs and employment,

and so then I quieted them down because when I told them that this was a very hotly contested hearing, there would be a lot of witnesses, and people were a little surprised.

In any case, I want to especially recognize Karen Lerner and Rich Lerner of Allcare Medical located in my district in New Jersey. Karen will be testifying before us today about the concerns of Medicare's program within the medical equipment community.

As you know, the Medicare program covers DME under Part B, the Supplementary Medical Insurance program, and pays suppliers according to a fee schedule. Commonly furnished items under this benefit include standard and power wheelchairs, oxygen concentrators and tanks, hospital beds, diabetic testing supplies and walkers. These and other DME items are essential treatment to allow the approximately 9.85 million Medicare beneficiaries with disabilities and other conditions to improve or maintain their health and to live independently at home.

Over the past several decades, numerous reports have documented overpayments in the DME fee schedule under Medicare. As such, Congress acted to limit these costs by creating a demonstration of the competitive bidding program in 1997. Its evaluation resulted in reduced costs to Medicare by 19 percent with no significant changes in access to supplies or changes in utilization were observed.

Subsequently, the Medicare Prescription Drug, Improvement, and Modernization and Act of 2003, which many of my colleagues on this side voted against, mandated that CMS adopt competitive bidding-based pricing for DME on a phased-in basis beginning in 2007. The Act mandated two rounds of bidding in MSAs, followed by optional additional MSAs after those rounds. As I, along with my colleagues witnessed, there were many problems with the initial implementation, coupled with broad industry concerns. This resulted in a bill that I led through Congress to both delay implementation and established some of the reforms that are supposed to be part of the program today.

Let me just briefly say that I have been skeptical of this program in the past, and I am anxious to hear from CMS about how this program is being run and, of course, how the round one re-bid is developing.

That being said I am also aware of the fact that CMS is carrying out the law as instructed by Congress. I know very well the concerns of the DME suppliers and it is my hope that CMS has done their best to address some of them. I think today will allow us to hear more about what CMS has done and continues to do to ensure that this program successfully reduces costs to Medicare but maintains access and quality care for Medicare beneficiaries.

It is obvious we cannot ignore what will become clear here today, and that is, there remains a large constituency that is simply opposed to this program, but meanwhile, the fear of tremendous consequences persists from both industry and from Members off Congress. So, regardless of where this committee falls, it is our job to keep a watchful eye of its development and be on guard to make changes if necessary.

My Rutgers class that caused me to be a little late today was very concerned about Congress exercising its oversight authority,

that somehow over the last generation or so we have not done enough for oversight, so I think we do need to do a lot of oversight and this is obviously part of that effort.

With that, I yield to the gentleman from Kentucky.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Mr. Chairman, thank you very much, and we look forward to this hearing, the opportunity to examine the impact of Medicare's competitive bidding program for durable medical equipment, and before I make a few comments about that, I would like to in a very respectful way touch on some of the questions that your Rutgers political science class were asking you.

All of us just came back from a 3-week district work period, and practically everywhere we went, people were asking questions about the recently passed health care bill, and almost all of them were unanimous in the fact that they did not understand the bill. They did not know when regulations were to be expected, when the bill would be completely into effect, and asking all sorts of questions that we really could not answer, and I genuinely believe it would be to the benefit of the American people if this committee did start having some oversight hearings on that legislation because it impacts every single person in this country, and I don't know of any legislation that has passed the Congress since I have been here in which people have been more confused than on this piece of legislation. And I know that the gentleman has the same concerns that I do but I do hope that we would have an opportunity to start having some hearings about that legislation.

Today we are very much interested in learning how this new competitive bidding program, this pilot project, is it really going to save Medicare money, and if it does, are we going to be able to maintain the quality of care for the beneficiaries, and I don't think there is any question but that we recognize in the long term we do have to do something about Medicare cost, not just for the fact of saving money, but if we are going to continue to have a viable health care system for our senior citizens, we have to be concerned about the quality of care as well as the price. And many experts that I have talked to, and I am certainly not an expert myself and I really don't have any opinion about this pilot project yet, but many of the experts have said that they believe that this pilot program is poorly designed. They say they have concerns that the entire program could collapse under its own weight, resulting in drastically reducing the number of health care providers in rural areas particularly as well as instead of decreasing cost increasing cost. By having a 3-year contract combined with the fact that relatively few providers are deemed winners results in fewer competitors the next time that bidding occurs because there is going to be a lot of people who will probably get out of this business.

But less competition also in the future may very well result in higher prices in the future and mitigate the projected savings by CBO. And as I said, we all are very much interested in solving some of these problems of cost and improving quality of care. And I don't intend to be negative about this today but I am delighted

that we are having the hearing to have a better understanding of really is this going to work and is it going to be effective.

And then I might also say recently some of us sent a letter to CMS asking that they provide a list of the winning bidders that won the first round of bids so that Congress might have the opportunity to examine those bids to see if those winners are in fact capable of participating in the program, and we only sent that letter a couple weeks ago so we have not had a response yet.

But I want to thank you again, Mr. Chairman, for the hearing and I look forward to the testimony of our witnesses who I know will provide us with information that we need to get an objective view of this program.

Mr. PALLONE. Thank you, Mr. Whitfield.

The chairman of the committee, Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Chairman Pallone for holding today's hearing on this important topic.

The health reform legislation contains many essential innovations to improve the quality and efficiency of care in Medicare and in fact the whole entire health care system. Today we are discussing an innovation that predates health reform: competitive bidding for durable medical equipment.

The DME benefit in Medicare is an essential benefit for the nearly 10 million seniors who use it ever year. It pays for wheelchairs to help seniors and persons with disabilities move around their homes and communities. It covers diabetic testing equipment so that beneficiaries can manage their condition and avoid kidney failure or heart disease.

DME is an indispensable part of an indispensable program. And yet, for many years, payments for DME in Medicare have been the source of seemingly endless problems. DME has received some truly remarkable overpayments. Take, for example, Medicare paying 10 times the purchase cost for oxygen equipment, and DME suppliers billing the program without even staffing their offices or documenting their claims gave us last year's famous "60 Minutes" program on Medicare fraud.

These chronic problems are an embarrassment to a program that has been, and must continue to be, a model for efficient health care purchasing. Many suppliers are legitimate, honest businesspeople trying to deliver the best care they can to Medicare beneficiaries. Their reputations are unfairly tarnished by the behavior of some of the other suppliers.

Congress has acted many times to try to address these problems. Some of these reforms have been successful, and some of them are just getting started.

Competitive bidding for DME is a market-based, bipartisan idea. It has been tested successfully in Medicare in demonstration programs under Presidents Clinton and Bush. And it was enacted for program-wide adoption in the Medicare prescription drug bill passed by a Republican Congress and signed by President Bush.

This current round of competitive bidding is a re-bid of round one, which was delayed in 2008. I supported that delay because of implementation problems identified at that time.

Acting under Congress's direction, the Centers for Medicare and Medicaid Services made many improvements to the re-bid of round one. Those changes appear to have reduced confusion among suppliers, though not opposition.

I take seriously the concerns raised by the supplier community regarding potential threats to beneficiary access to high-quality DME. Competitive bidding has been tested successfully in Medicare, but not on a scale as large as what the law requires CMS to implement over the next few years.

It is essential that we on this committee continue to monitor developments in this competitive bidding program as it unfolds. That is why I appreciate Chairman Pallone's initiative in calling this morning's hearing.

It is also essential that CMS aggressively pursue supplier and beneficiary education efforts in the time before January 1, so as to minimize disruption to care with the start of the New Year.

But I question those who say that we need to repeal the program now because of speculative threats to beneficiary access in the future. Where is the evidence for such a threat? It is certainly not found in previous experience with competitive bidding in the Medicare program.

Tellingly, those most concerned about beneficiary access—the beneficiaries themselves, including AARP and the Center for Medicare Advocacy—support going forward with the program and vigorously monitoring its execution.

Based on what we've heard so far, it appears that the current round of competitive bidding will save beneficiaries significant amounts of money in cost-sharing and premiums. Beneficiaries using oxygen concentrators over a 3-year rental period would save $400. And the improvements made by Congress and CMS offer important guarantees that winning suppliers will be able to deliver items and services beneficiaries need. For these reasons, I am cautiously optimistic that competitive bidding for DME may soon begin to finally achieve its promise of reducing Medicare spending while maintaining or improving the quality of care received by beneficiaries.

I would also like, Mr. Chairman, to ask unanimous consent to add to the record this statement from AARP that supports competitive bidding so long as it does not compromise quality and access for Medicare beneficiaries.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. WAXMAN. And look forward to this morning's hearing.

[The prepared statement of Mr. Waxman follows:]

Opening Statement of Chairman Henry A. Waxman
Committee on Energy and Commerce
Subcommittee on Health
Hearing on "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access"
September 15, 2010

I thank Chairman Pallone for holding this hearing on this important topic.

I'd also like to ask unanimous consent to add to the record this statement of support of competitive bidding from the AARP. (can we do that in a statement?)

The recently enacted health reform legislation contained many essential innovations to improve the quality and efficiency of care in Medicare and the entire health care system. Today we discuss an innovation that predates health reform – competitive bidding for durable medical equipment.

The durable medical equipment benefit in Medicare is an essential benefit for the nearly 10 million seniors who use it ever year. It pays for wheelchairs to help seniors and disabled people move around their homes and communities; it covers diabetic testing equipment so that beneficiaries can manage their condition and avoid kidney failure or heart disease. DME is an indispensible part of an indispensible program.

And yet, for many years – nearly as long as I've been here, in fact – payments for DME in Medicare have been the source of seemingly endless problems. It's DME has seen some truly remarkable overpayments: for example, paying 10 times the purchase cost for oxygen equipment. It's DME suppliers in many areas billing the program without even bothering to staff their offices, or to document their claims, that gave us the famous 60 minutes program on Medicare fraud last year. These constant problems are an embarrassment to a program that has been, and must continue to be, a model of efficient health care purchasing.

Congress has acted many times to try to address these problems. Some of them have been successful, and some of them are just getting started. Health reform contained many provisions that will help confront fraud across the entire program, including the DME benefit.

Competitive bidding for DME is an idea that has been tested successfully in the Medicare program in demonstration programs under Presidents Clinton and Bush. It was slated for program-wide adoption in the Medicare prescription drug bill.

This current round of competitive bidding is a re-bid of Round 1, which was delayed in 2008. I supported that delay in because of implementation problems identified at that time, including unclear biding instructions, unlicensed suppliers winning contracts, badly performing bidding software, and generalized confusion among suppliers. Soon after the delay, the GAO confirmed that many of the problems we had noticed were real.

Acting under Congress's direction, CMS made many improvements to the re-bid of round 1. Bidding instructions have been improved, software has been upgraded, and additional time has been allotted for supplier education. The GAO notes in its testimony that these changes have addressed many of its concerns from the initial Round 1.

I take seriously the concerns raised by the supplier community regarding potential threats to beneficiary access to high quality DME. Competitive bidding has been tested successfully in Medicare, but not on a scale as large as what the law requires CMS to implement over the next few years. Accordingly, it's essential that we on this Committee continue to monitor developments in the program as it unfolds, and I intend to do so. It is also essential that CMS aggressively pursue supplier and beneficiary education efforts in the time before January 1 so as to minimize disruption to care with the start of new

But I question those who say that we need to repeal the program now because of speculative threats to beneficiary access in the future. Where is the evidence for such a threat? Previous experience in the Medicare program lends no support to the idea; and beneficiary advocacy groups, including the AARP and the Center for Medicare Advocacy, support going forward with the program.

It appears that the current round of competitive bidding will save beneficiaries significant amounts of money in cost-sharing and premiums – over $400 for a beneficiary using oxygen concentrators over the 3-year rental period, for example. And the improvements made by Congress and CMS appear to offer important guarantees that winning suppliers will be able to deliver on their promises.

Accordingly, I am cautiously optimistic that competitive bidding for DME may soon begin to finally achieve its promise of reducing Medicare spending while maintaining or improving program quality.

Mr. PALLONE. Thank you, Mr. Chairman.
Next is the gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you.

As far back as the Balanced Budget Act of 1997, Congress has attempted to address the cost of durable medical equipment on American taxpayers. In large part, Congressional action was prompted by investigations that highlighted a Medicare program paying way above market prices for certain durable medical equipment items. Such overpayments may be due to a Medicare fee schedule that is outdated, lacking what MEDPAC calls "the invisible hand of market forces" that can keep costs down. This antiquated system hurts our taxpayers. It makes it hard for seniors to find a provider or a service when sick and it undercuts financial solvency of the Medicare program.

The mechanism passed to correct this payment issue, the DME competitive bidding program, was passed with bipartisan support in Congress. However, some concerns arose with the manner in which CMS was conducting the program and some businesses were disadvantaged. I am sensitive to those concerns as I believe that DME companies should be competitive with market prices and not be protected by government rates at the expense of we, the taxpayer.

However, I also believe that government programs should allow DME companies to compete and not completely block the market to so many, particularly the small entrepreneurs. These are the principles of a free market economy that MEDPAC suggests Medicare lacks and principles I believe we should all support.

Therefore, I want to thank Chairman Pallone for calling this hearing today and I certainly look forward to hearing from our witnesses.

That being said, Mr. Chairman, I would like to ask again that this committee call a hearing on Obamacare as soon as possible because the news of its impact on Americans is getting worse. Just this week, Secretary Sebelius sent a letter to various health insurers condemning them for almost double-digit premium increases for the coming year. In that letter, the Secretary called reports of planned premium increases to reflect the new mandated benefits in the law, and I quote "misinformation and unjustified rate increases." Mr. Chairman, I think it is important that we figure out what is going on here. Why are health insurers raising costs by 10 percent if Obamacare is supposed to reduce cost? An op-ed in the Wall Street Journal on Monday states that, and I quote, "The tone of Ms. Sebelius's letter suggests that she doesn't understand that if Congress mandates new benefits, premiums will rise."

Mr. Chairman, my question is this: Is Secretary Sebelius looking out for the American patients or is she covering up the fact that Obamacare is making their health care unaffordable? I believe the American people and this Congress deserve to know whether these huge rate increases are the work of bad insurance companies or the result of Obamacare. This committee did not shy away from vili-

fying insurance companies in the past. I see no reason why it should shy away from holding a hearing on this issue now.

With that, Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you.

Next is the gentleman from Texas, Mr. Green.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing today on Medicare's competitive bidding program for durable medical equipment.

Medicare Part B covers a wide variety of durable medical equipment that is prescribed by physicians for beneficiaries including prosthetics, orthotics, oxygen, wheelchairs, diabetes testing strips, medical dressings and other various medical supplies. According to the Congressional Research Office, in April 2009 there were 107,000 durable medical equipment suppliers in the United States with Medicare billing privileges. Medical expenditures for durable medical equipment were $10.6 billion in fiscal year 2008. In 2009, approximately 9.85 Medicare beneficiaries used Medicare-covered durable medical equipment.

In general, Medicare pays for durable medical equipment on a fee schedule updated each year by inflation. However, several reports including investigations by the GAO, MEDPAC and the Office of Inspector General have shown Medicare pays above market prices for certain items of durable medical equipment. These overpayments have been linked in part to a fee schedule payment system which does not take into account market changes.

To remedy these systematic overpayments, two demonstrations were conducted and a new system of competitive bidding for durable medical equipment. However, this new system implemented in 2007 by MMA was unsuccessful in monitoring, causing confusion among suppliers including CMS delaying the bid window, providing unclear instructions to bidders and electronic document systems that failed and failed to notify suppliers when bidding was complete. This caused Congress in 2008 to halt the program until 2009 so CMS could resolve the issues within the competitive bidding program.

CMS allowed suppliers to submit new bids for the first round rebid in late October 2009 until December 2010, and in July 2010 announced initial payment amounts and contract winners. Final contracts and lists of suppliers of the first round of re-bidding will be announced this fall and contract will go into effect in January.

I think this hearing is especially important because Congress has so many concerns with the initial bidding process, and we want to ensure that the next go-around will be successful. We want to ensure Medicare Part B beneficiaries continue to have access to durable medical equipment. We also want to ensure we are not raising their premiums because of the waste or fraud in the system or because of overpricing. All new programs and systems have some problems that need to be addressed. Hearings like this are important because we have the duty to ensure Congressionally implemented programs are working and benefiting many Americans.

I look forward to the testimony today and I want to thank the witnesses for taking the time to appear, and Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you, Mr. Green.

The gentleman from Pennsylvania, Mr. Pitts.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Thank you, Mr. Chairman.

Medicare generally pays for most durable medical equipment—prosthetics, orthotics and supplies—on the basis of fee schedules. Unless otherwise specified by Congress, fee schedule amounts are updated each year by a measure of price inflation. However, investigations have shown that Medicare pays above market prices for certain DME items.

The Medicare Modernization Act of 2003 established a competitive bidding program for certain DME items which began in 2008 only to be halted days later due to implementation concerns. All contracts with suppliers were terminated and round one of the competitive bidding program had to be re-bid. The second round of bidding is schedule to begin early next year.

CMS now estimates that Medicare will pay on average 32 percent less for items in the competitive bidding program than it would pay for those same items under the current fee schedule. However, patients and suppliers have concerns that the competitive bidding process will reduce access to quality items and squeeze smaller suppliers out of the market.

I would like to hear from our Administration witnesses and stakeholder witnesses on how they view the program and how Congress can make improvements to ensure that patients have access to DME items they need while Medicare isn't overcharged.

This is a very important hearing. I look forward to hearing the testimony. Thank you, and I yield back.

Mr. PALLONE. Thank you, Mr. Pitts.

Our chairman, Chairman Emeritus, Mr. Dingell.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you, and I commend you for this hearing and I thank you for holding it. A number of us on the committee requested it because of our concern about whether or not the competitive bidding program is going to in fact work.

First of all, it has, as you know, proven to be a very controversial topic, not just among the members of the committee but amongst suppliers, beneficiaries and providers across the country. In the midst of all of this back and forth, I am hopeful that the two sides can agree on two important points: one, the pricing and integrity issues in the Medicare DME are a cause for concern and need to be addressed for the sake of the fiscal future of Medicare and to hold down the costs for beneficiaries, and second, when legitimate problems with implementation of the competitive bidding program are identified, that Congress has acted to address these problems.

Today's hearing is going to give us a good opportunity to assess the current state of the Medicare DME competitive bidding program, its cost and the impact on the impact on cost and quality and access and lessons learned and opportunities for improvement. We should have a clearer understanding of what, if any, changes should be made in the program as it is expected to expand.

Though this morning's hearing is not specific on any particular piece of legislation, I must mention the legislation that I introduced last month to address a very legitimate concern raised by hospitals in Michigan and others throughout the country. Many hospitals have developed their own DME companies in an effort to better integrate hospital care and support the efficient management of the discharge process. I am concerned that the competitive bidding program threatens the ability of hospitals to continue to operate. H.R. 6095 would allow the hospital-based DME providers to continue serving their entity's patients while being at the same time compensated at the competitively bid rate.

Let me make two things very clear. First, H.R. 6095 would require those hospital-based DME providers to pay these prices negotiated through the competitive bidding process, and two, the providers would be only allowed to supply patients of their hospital or affiliated physicians. H.R. 6095 enjoys the support of the American Hospital Association and the Premier Health Care Alliance.

Mr. Chairman, I ask unanimous consent to have the letter from AHA and Premier in support of H.R. 6095 inserted into the hearing record.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. DINGELL. I have the particular pleasure to welcome Nancy M. Schlichting to the committee this morning. Nancy is an extraordinarily capable woman. She is the President and Chief Executive Officer of Henry Ford Health System, one of our Nation's premier health care providers. For many years Henry Ford has been committed to improving the health and well-being of the diverse Michigan community. Nancy Schlichting and the Henry Ford Health System has been an enormously valuable resource to us in Michigan and to me on many important health issues, and I am sure she will prove herself to be every bit as valuable to the members of this committee on this important issue.

I want to thank you again, Mr. Chairman, for obliging my request to have Ms. Schlichting with us today and I know she will be bringing much value to this very important hearing.

I thank you, and I yield back the balance of my time.

Mr. PALLONE. Thank you, Chairman Dingell.

The gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman.

This provision created in the Medicare Modernization Act to create the competitive bidding program, it is hard to say you don't support the goals of fair and equitable pricing for medical devices for patients and at the same time reducing inappropriate transfers. Certainly the idea holds promise and takes the fundamental free

market principle and puts it into practice, allowing businesses to compete to general cost savings.

We all know something needed to be done prior to the Medicare Modernization Act. The work of this committee demonstrated that Medicare beneficiaries were paying prices that were frankly too high. However, the execution of this attempt to address a very real problem has created problems of its own. To say that the program was poorly executed would be being unnecessarily kind. Fault lies with CMS. The Government Accountability Office has found widespread challenges to suppliers, and I am quoting here, "including poor timing and lack of clarity in bid submission information, a failure to inform all suppliers that losing bids could be reviewed, and an inadequate electronic bid submission system." Reports of winners who were unlicensed and unaccredited and realistically unable to serve a geographical region and showed a widespread reduction in the majority of providers in each of the competitive bidding areas. A fee schedule based on these bids thus really cannot be considered to be a valid fee schedule at all.

The first attempt at round one ran for 2 weeks. It was stopped by Congress famously on July 15, 2008, because of some of these concerns. The Government Accountability Office called these results unclear and inconsistent. However, when round one was restarted, for many it was more like getting to replay the same hand of cards when everyone knew what everyone else's cards were. So it really was a process that was deeply flawed.

I do not believe it is Congress's jobs to guarantee a business's income. At the same time, a winner unable to complete the job drives out competitors and leaves the beneficiary with nothing. What the program was supposed to accomplish was equal access for lower cost, and it really looks as if the Center for Medicare and Medicaid Services didn't take the first part of that equation seriously at all. CMS should look at a company's previous year's market share and geographic reach when considering awarding contracts while allowing for desired company growth. However, it is my guess that a company that is accustomed only to serving, say, a very small town in my district may not be able to service the entire DFW metroplex overnight. It is a simple condition we call common sense.

Now, Congress will have to explore what is the best policy to contain cost while not threatening access. That may mean a new policy or it may just mean that Congress needs to stay out of the way and see if the market can adapt to the CMS rules, knowing that we will not interfere. I am not sure which direction is best at this point but I certainly look forward to our witnesses for guidance.

Mr. Chairman, I would also ask unanimous consent for testimony for the record from ConvaTec, a medical device company specializing in osteotomy care and wound therapeutics, be entered into the record.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. Thank you.

Mr. PALLONE. Thank you, Mr. Burgess.

Next is our colleague, the gentlewoman from Colorado, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman. We are all a little rusty coming back after 6 weeks.

I am really happy also that you have had this hearing today, and truly I am looking forward to hearing the testimony because like all of the members of this committee, we are concerned about saving money for our seniors and we are also concerned about the investigations that show that Medicare pays above market prices for certain durable medical equipment. And the competitive bidding demonstration did result in a savings but on the other hand, there are a lot of anxieties about implementation and the expansion from nine to an additional 80 areas including my district of Denver most likely, and the round one bidding process had a lot of complications, as we have heard from our colleagues. So we need to make sure that the guidelines for suppliers and information disseminated to beneficiaries is clear and consistent before we expand the bidding process, and we also have to ensure that Medicare beneficiaries can receive the same quality of medical equipment that they are accustomed to and also we need to make sure that we have enough suppliers.

So there are a lot of issues here and I am glad you are having this hearing so we can begin sorting them out, and I yield back the balance of my time.

Mr. PALLONE. Thank you.

The gentlewoman from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. Thank you for the hearing today.

You know, Medicare's competitive bidding program for durable medical equipment has been contentious, to say the least, and many issues in this competitive bidding program are worthy of discussion and should be discussed. We need to talk about access, transparency, accountability and the impact on small businesses, and many of my constituents have very grave, solid and valid concerns on the implementation of the program.

While the DME issues are worthy of discussion, we continue to hear disturbing news about the implementation of Obamacare. News broke last week that I believe deserves urgent attention from this committee. Public opinion is heavily against the program. The Obama Administration is dealing with fuzzy math regarding soaring health care costs, and Health and Human Services Secretary Sebelius is trying to bully insurance companies into submission.

Now, since that bill passed, we have had 15 Health hearings, seven O&I hearings, and not one of those, Mr. Chairman, has been on the implementation of Obamacare. We need to remedy that.

Last week, Secretary Sebelius sent what I think is a fairly threatening letter regarding rate increases resulting from new regulations and mandates in Obamacare. Apparently insurers aren't supposed to explain the cause and effect of that program to their

consumers including rate increases with 1 percent upwards to 16 percent in some areas. The Administration's attempt to muzzle private companies from explaining to their customers such rate increases as a result of Obamacare I find to be the height of hypocrisy and irresponsibility. That anyone is surprised that costs are rising rapidly under Obamacare is beyond me. We are talking basic economics, the laws of supply and demand. There is no such thing as free care. It has to come from somewhere and it has to be paid by someone.

As I have detailed in countless hearings, we tried this in Tennessee. I have tried to explain this to the President, to the Secretary and my colleagues on the other side of the aisle. TennCare was supposed to expand coverage and save money. In 10 years, it nearly bankrupted the State of Tennessee. TennCare didn't save money. It didn't expand coverage as promised and ultimately more than 100,000 people had to be removed from that program.

As Tennessee learned, comprehensive health care packages for all will not also be affordable. Government's resources to provide care are fixed. As we learned, intervention can exacerbate rather than control the growing costs of health care. I would love to see us reviewing this issue.

I yield back.

Mr. PALLONE. Thank you, Ms. Blackburn.

Next is the gentleman from Georgia, Mr. Barrow.

Mr. BARROW. I thank the Chair. In the interest of time, I would like to ask unanimous consent to have 5 legislative days to submit my statement for the record.

Mr. PALLONE. Without objection, so ordered.

Mr. BARROW. Thank you.

[The prepared statement of Mr. Barrow follows:]

Rep. John Barrow
Statement for the Record
Energy and Commerce Health Subcommittee Hearing
Competitive Bidding and DMEPOS
September 15, 2010

Mr. Chairman,

I've been disappointed with recent developments in CMS's competitive bidding program for durable medical equipment. I recognize the need to weed out the bad providers and the fraudsters. I don't think there's any question that they're costing taxpayers billions. But I fear that the measures we're employing to deal with the bad guys are killing the good guys in the process. As this process has developed I've had the opportunity to get to know some of the good medical equipment providers in my district. These are the people on the frontlines. They have relationships with their patients. They know their needs and they go the extra mile to meet those needs. I don't think there is any question that that kind of service leads to better outcomes, and ultimately to reduced costs. Ironically, there's a real risk that the competitive bidding process ends up putting all the good guys out of business, leaving nothing but the bad to carry the weight of the entire system. That's counterproductive. I submit that there are better reforms and better ways to find savings that preserve our best quality equipment providers. I thank the Chair and I yield back.

Question for the Record:

I can envision a scenario where new technologies and treatments could become available in between the three year competitive bidding windows. Many of these supplies tend to evolve rapidly. How do you plan to address the problem of access to new technology that is developed outside the three-year bidding cycle? Will there be a mechanism to reimburse for equipment when the technology becomes available?

Mr. PALLONE. And next is the gentleman from Texas, Mr. Hall.

OPENING STATEMENT OF HON. RALPH M. HALL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. HALL. Mr. Chairman, thank you, and thanks for having the hearing.

The issue of most concern to me is the lack of accountability. When an out-of-area and inexperienced provider can be in any area they choose, undercut the market and withdraw from the program without any repercussion is very, very disturbing.

But what is stunning is that CMS, I am told, then used the abandoned low bids as a new rate and required other so-called winners to adhere to a bid that they did not make. CMS claims that it is a market-based program but contrary to their claims, providers are forced lest their close their business to accept prices 20 to 50 percent of what they bid.

Many are closing their doors and some are accepting contracts for the sole purpose of staying in business with no profit or at a loss until the program fails and the proper health care can be restored. These are not proper business practices and the program was never intended for this scenario.

It must be noted how flawed the program is when the Nation's largest provider, Lincare, put out a press release stating that they were offered contracts over 20 percent less than their bids if they would accept the contracts even though they would lose money on each Medicare patient and would have to supplement these patients from the income they received from other non-Medicare patients. I would like to submit this press release in the record with your permission, Mr. Chairman.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. HALL. Transparency of the bidding program has a major problem throughout this process. CMS has refused to release the names of the companies that set the bid rate. This information is necessary so it can be determined if those companies are local or out of the area, experienced, or if those companies are financially viable. Without transparency, the program cannot be fairly evaluated and the bids must be circumspect. CMS seems to be hiding the many known flaws and problems until after the program is implemented.

Here is a letter that I along with 135 of my colleagues sent to CMS requesting their names of the winning bidders, and here is CMS's response denying our request. With your permission, Mr. Chairman, I would like to submit these into the record.

Mr. PALLONE. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. HALL. CMS has claimed that they have performed the diligence on providers and have assured that bidders are financially qualified yet companies such as Rotech were able to win bids that averaged 30 percent below their current rates, even though at a current rate they are technically bankrupt. Other companies that are in financial trouble have won bids as well. In fact, when asked about the questionable financial viability of companies who were awarded bid contracts, Laurence Wilson of CMS stated on the

record that 30 percent of the bidding companies had questionable financials but CMS allowed them to proceed through the process.

This disregard for their own directives reveals much about the flaws in the bidding program. CMS has allowed bid rates to be created that are functionally unviable. The average single payment amount for portable oxygen, oxygen tanks that allow patients to leave their homes and lead a normal life, is averaging $21 a month while the actual cost to provide a liquid portable system is over $100 a month. An additional oxygen delivery service cost brings the actual monthly cost to over $150 a month. Providers will have no choice but to stop providing liquid oxygen, which will result in the suffering of patients.

In a similar vein, diabetic supply price reductions are averaging over 54 percent of their current reimbursement. No industry in America can survive such a cut.

In closing, I will just stay at best that CMS required cut will mean that only foreign-made supplies with less reliability will be used by Medicare patients. American-made products will no longer exist. An immediate service which is often required by patients will be replaced by ground freight delivery. This is disgraceful.

Thank you again for having this hearing today and I yield back the balance of my time.

Mr. PALLONE. Thank you, Mr. Hall.

Next is the gentleman from Iowa, Mr. Braley.

OPENING STATEMENT OF HON. BRUCE L. BRALEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. BRALEY. Competitive bidding. It sounds like it would be un-American to oppose something that sounds so important and yet competitive bidding will lead to the now-disproven model of too big to fail in the durable medical equipment industry because companies that can lower margins and try to make it up on volume are going to drive providers out of the market in places like my State of Iowa. We know that is going to happen. You don't need a Ph.D. to figure that out.

The competitive bidding program has been plagued with problems from the beginning. Even proponents of the program readily admit that the implementation process was problematic. CMS delayed the bid window deadline several times, provided bidding instructions while the bidding window was open, sometimes provided unclear guidance to bidders, operated an electronic document system that failed frequently, and didn't notify suppliers that their bid information was incomplete. Put frankly, this program has a poor track record.

Now we have evidence of the devastating impact on beneficiaries like my constituents who depend on medical supplies, especially in rural areas. A recent study by Dr. Kenneth Brown, a professor of economics at the University of Northern Iowa, concluded that the competitive bidding program for DME will have a significant negative impact on rural areas, which are specifically excluded from the bidding process. Dr. Brown reached this conclusion based on a study of the current state of the industry, the financial results across the industry and the 32 percent average reduction in reimbursements that is resulting from round one bids. Specifically, Dr.

Brown believes that my home State of Iowa will lose 40 to 50 percent of its DME suppliers in the aftermath of competitive bidding. That is unacceptable to me and the people I represent.

Now, despite the data and track record, CMS has moved forward again on its round one re-bid and the problems are surfacing again. In addition to questions about the impact in rural areas, other questions have arisen about the level of transparency in the process so far, and this is a bipartisan issue that almost 150 of my colleagues have raised concerns about. I would hope that CMS would go above and beyond to provide full and open transparency into the bidding process, which has been a high priority of the President. Unfortunately, the vital information is unavailable for both Congress and the program advisory and oversight committee about how those rates have been determined, access to care for beneficiaries and the impact on small providers.

For all of those reasons, Mr. Chairman, I am glad you decided to hold the hearing and I look forward to having many of these questions finally getting the answer they deserve.

And last, I would like to request unanimous consent to submit the following items to the record: Dr. Kenneth Brown's study on the impact of competitive bidding in rural areas, testimony by Jim Tozzi, a member of the board of directors of the Center for Regulatory Effectiveness, and on behalf of Representative Jay Inslee, a letter from Care Medical and Rehabilitation in Seattle, Washington.

Mr. PALLONE. Without objection, so ordered.

[The information was unavailable at the time of printing.]

Mr. BRALEY. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Braley.

Next is the gentlewoman from Ohio, Ms. Sutton.

OPENING STATEMENT OF HON. BETTY SUTTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Ms. SUTTON. Thank you, Mr. Chairman, for holding this very important hearing today.

This hearing is not only about access to the health care for the American people but it is also about jobs and it is about our economy. It is about our seniors, veterans and other patients and their ability to access wheelchairs and oxygen tanks and other durable medical equipment. This equipment is often essential for their survival. Many of these patients in need are covered by Medicare, Medicaid and TRICARE, and this process will make a difference in whether they will continue to have access to the equipment they need and the help that they need.

Today we are here to review the current durable medical equipment bidding process and determine whether it works for and with our patients and for our small businesses. While restructuring the durable medical equipment bid program is necessary to prevent the waste, fraud and abuse in the system, it must not be done at the expense of losing thousands of jobs and preventing patients from accessing what they need.

For manufacturers and suppliers, the transition to the so-called competitive bidding program has been complex and time consuming, and the irony of it all is it is not competitive. Knowing as

much information as possible is crucial to submitting bids. CMS's plan to overhaul the system is well intended but must be done carefully and sensibly. Initial attempts by CMS to implement the first round of competitive bidding were seriously flawed, and as a result the requirement to resubmit all round one bids has delayed the entire program by 2 years but CMS is already preparing for round two. If this is truly being done in the spirit of transparency and before we move to round two, we need to know who are the recipients of round one bids. CMS has failed to identify them, even after 136 Members of Congress formally asked for the information. Thirteen of those members are from Ohio.

The process must be immediately reviewed and changed. In my district alone, thousands of jobs are at stake, and in the State of Ohio thousands more are at stake. So let us be clear. Our country needs to continue making things here. We must not create a new bidding process that is less transparent and encourages American businesses to move overseas. We want to encourage businesses to keep making their products right here and right in Ohio where I am so proud to represent. And at the end of the day, if we don't fix this process, our manufacturers will suffer, our employees will suffer and our patients will suffer. It doesn't have to be that way but it is critically important that we get it right.

I thank you for having the hearing, and I yield back the balance of my time.

Mr. PALLONE. Thank you.

Next is the gentlewoman from California, Ms. Eshoo.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Thank you, Mr. Chairman. I along with all the members of the subcommittee thank you for holding this important hearing on Medicare's competitive bidding program for durable medical equipment. It is important for the committee to examine the status of this program which for years has seen the mismanagement and the fraud that has been a part of it. This is all carried by Medicare. Anyone that cares about Medicare and its solvency as well as seniors owe something to the examination and that is what we are doing today.

We all know that durable medical equipment covers products that range from wheelchairs, oxygen concentrators, hospital beds, walkers and diabetic testing supplies. These are all essential health care products and beneficiaries are responsible for paying the other 20 percent in addition to any unpaid deductible. I am familiar with every single one of these products with the exception of the diabetic testing supplies. I had to get them for either my mother or my father or for both, so I am very familiar with who I went to, who delivered, what they cost, what the rental costs were, all of that, because I was in charge of their care.

There is inflated costs that hurt seniors directly and not just the Medicare system as a whole. We place value on the importance of comprehensive quality care for the elderly in our country and the rates of fraud and abuse that the GAO has uncovered, in my view, are sickening.

I just want to give some examples. In 2006, the HHS Office of the IG reported that Medicare would allow $7,215 in payments over 36 months to oxygen suppliers for oxygen concentrators that cost $587 on average to purchase. In 2009, the OIG reported that in 2007 Medicare allowed $4,018 for standard power wheelchairs that cost suppliers $1,048 to acquire. Anyone that stays up late at night sees these advertisements for wheelchairs and that they will guarantee that Medicare picks up the entire tab for it. So I am not against Medicare making payments for these things, but you know what? I think we all need to recognize that something is not right in this.

So this examination today is a very important one. I think the early indicators are positive that the new competitive bidding process is working. I understand that suppliers don't like it, but this is a new day. We have the responsibility to extend the life of the trust fund of Medicare. I have heard an unending chorus relative to the new health law and saying all kinds of things about Medicare. This is an area where like it or not, we have to find ways to save money, find new ways to do the old things in a better way and save money and still take good care of people. We have had a system where people are used to it, made a lot of money on it. I think that there has been documented abuse of that system.

So I hope what we learn today is, what is working, what isn't and what we can improve upon as we move forward. But I think central to this really must be the cost to Medicare and the cost to seniors. Medicare doesn't pick up the whole tab for this, but as one member I am convinced that we can do this in a much better way and save money. I think that is already documented by the IG.

So thank you for having this hearing, Mr. Chairman, and I look forward to the discussion and the debate.

Mr. PALLONE. Thank you, Ms. Eshoo.

And last, I believe, is the gentlewoman from Florida, Ms. Castor.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Good morning, Mr. Chairman, and thank you very much for convening this hearing today.

The durable medical equipment competitive bidding program is of great concern to both patients and suppliers in my home State of Florida, so I am pleased today that we are going to take a closer look at what is happening.

Florida is among the areas most affected by the DME bidding program. In my Tampa Bay area community, the greatest concerns about the bidding program deal with fairness. Longstanding local suppliers now find themselves in trouble because they are losing bids to larger companies outside of the community and often out of state. According to the Florida Alliance of Home Care Services, out-of-area companies without experience bid at prices that are far below the cost of local services and then later walk away from their bids, causing great turmoil.

Other concerns surround the program's efficacy in actually targeting fraud in the right way. There are claims that some of the companies that have been awarded bids are under fraud investigation or have settled fraudulent claims with a large payout, and in

Florida where the MEDPAC has identified, and we all know it, huge geographic disparities in Medicare spending, especially in DME in certain parts of Florida, we have got to make sure that if we are targeting fraud we are doing it in the right way.

Competitive bidding can be great, as my colleague said from Iowa. It sounds great. But we have got to make it work. It can't just be totally arbitrary. If we are going to have competitive bids, is it right that companies that have been involved in fraud before Medicare are taking some of these bids away from our local suppliers that have a proven history.

Today's hearing is critical to really getting to the bottom of these issues and let us get a better understanding.

So at this time, Mr. Chairman, I would like to ask unanimous consent that the committee receive for the record a statement of my colleague, Ron Klein from Florida, regarding the topic of concern today.

Mr. PALLONE. Thank you, Ms. Castor.

Ms. CASTOR. I ask unanimous consent.

Mr. PALLONE. Absolutely. Without objection, so ordered.

[The information appears at the conclusion of the hearing:]

Ms. CASTOR. I yield back.

Mr. PALLONE. And if any other member wants to submit a statement for the record, we will obviously have no problem with that, if any other member wishes to do so.

Now, that ends our opening statements by members of the subcommittee so I would ask our first panel to come forward at this time, if you would. Let me welcome all of you and introduce each of you. On the first panel, beginning on my left, we have Mr. Laurence Wilson, who is Director, Chronic Care Policy Group of the Center for Medicare and Medicaid Services with U.S. Department of Health and Human Services. Next we have the Hon. Daniel Levinson, who is Inspector General from the Office of the Inspector General again with the Department of Health and Human Services. And lastly is Ms. Kathleen King, who is Director of Health Care for the U.S. Government Accountability Office.

I think you, we try to keep the opening statements to 5 minutes and then those statements become part of the record, and of course, if you want to submit additional brief or pertinent statements in writing for inclusion in the record, you may do so. And so I will start with Mr. Wilson.

STATEMENTS OF LAURENCE WILSON, DIRECTOR, CHRONIC CARE POLICY GROUP, CENTER FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; HON. DANIEL LEVINSON, INSPECTOR GENERAL, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND KATHLEEN KING, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF LAURENCE WILSON

Mr. WILSON. Good afternoon, Chairman Pallone, Ranking Member Whitfield and distinguished members of the subcommittee. I am pleased to be here today to discuss the durable medical equip-

ment, prosthetics, orthotic supplies competitive bidding program. This important initiative required under the Medicare Modernization Act of 2003 and recently expanded under the Affordable Care Act will reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare's payments, help combat fraud and ensure beneficiary access to high-quality items and services.

CMS initially implemented the program on July 1, 2008, in 10 metropolitan areas. After 2 weeks of operation, the program was delayed by the Medicare Improvements for Patients and Providers Act. CMS has examined the program closely including lessons learned from the initial round of bidding in 2008. We have made the changes required by law and many other significant improvements and are prepared to implement the re-bid of the program on January 1, 2011. We will do so in a way that ensures a smooth transition for beneficiaries and suppliers while providing effective oversight and monitoring.

CMS had worked closely with stakeholders including its external advisory committee to design and implement the competitive bidding program in a way that is fair for suppliers and sensitive to the care needs of beneficiaries. For example, the program includes provisions to promote small supplier participation and numerous protections for beneficiaries. As designed, the program results in a large number of winners so that beneficiaries have a choice and there will continue to be competition among contract suppliers on the basis of customer service and quality.

In addition, quality standards and accreditation combined with financial standards provides safeguards to support good quality and customer service while acting to weed out illegitimate suppliers and ensure a level playing field for suppliers competing under the program.

CMS made a number of important improvements to the program in preparation for the re-bid in nine areas of the country. These changes provide for a fair process and more effective scrutiny of suppliers' qualifications and the integrity of their bids. For example, CMS initiated a comprehensive bidder education campaign much earlier in the process. CMS developed a more user-friendly online bidding system, which did not experience the glitches that troubled bidders in 2007. MIPPA mandated a process to alert bidding suppliers if they were missing certain financial bid documents. This was very effective with three-quarters of suppliers taking advantage of the process. CMS verified bidders' compliance with all state licensure requirements early in the bid evaluation process and CMS improved its process for evaluating bids to ensure they reflect a bona fide amount that a provider can provide an item for.

CMS also carefully reviewed the capacity of each supplier to provide services. New suppliers and those that told us they could greatly expand their businesses received higher scrutiny. These and other changes helped ensure that payment amounts are based on realistic bids and that there would be more than enough qualified suppliers to serve patients. These process improvements also tend to favor local experienced suppliers. For example, 73 percent of contract offers made on July 1 went to suppliers with a history of providing the specific product in the local area. A full 95 percent of offers went to experienced suppliers.

Our experience with the round one re-bid has also shown that competitive bidding has the potential to bring value to Medicare beneficiaries and taxpayers compared to the current fee schedule. In fact, average savings across the nine metropolitan areas is 32 percent. This translates into $17 billion in savings to Medicare over 10 years and another $11 billion in savings for beneficiaries through lower coinsurance and premium reductions. As a specific example in my Miami, the price of a standard power wheelchair will drop $1,274.

In the coming weeks, we will complete the contracting process and publish the names of the new contract suppliers. At the same time, we will ramp up our outreach and education efforts focusing on beneficiaries, referral agents, suppliers and others. As with any new program, we recognize this is a change for suppliers and patients. We will monitor implementation closely and are prepared to act swiftly to address any concerns that may arise on behalf of beneficiaries and suppliers. We have a network in place built around our national competitive acquisition ombudsman, local ombudsmen, regional office CMS caseworkers, contractors and Medicare call centers to address and track questions and concerns. We will also survey beneficiaries and perform active claims surveillance aimed at ensuring Medicare beneficiaries are receiving quality care.

In summary, we will be diligent and thoughtful in our implementation of the program and continue to work closely with our stakeholders. Again, I appreciate the invitation this morning to testify before you and would be happy to take any questions. Thank you.

[The prepared statement of Mr. Wilson follows:]

STATEMENT OF

LAURENCE D. WILSON

DIRECTOR
CHRONIC CARE POLICY GROUP, CENTER FOR MEDICARE
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

MEDICARE'S COMPETITIVE BIDDING PROGRAM FOR DURABLE MEDICAL EQUIPMENT: IMPLICATIONS FOR QUALITY, COST, AND ACCESS

BEFORE THE

U.S. HOUSE COMMITTEE ON

ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH

SEPTEMBER 15, 2010

U.S. House Committee on Energy and Commerce

Subcommittee on Health

Hearing on "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access"

September 15, 2010

Chairman Pallone, Ranking Member Shimkus, and distinguished members of the Subcommittee, I am pleased to be here today on behalf of the Centers for Medicare & Medicaid Services (CMS) to discuss the competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), which was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and modified by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and the Affordable Care Act of 2010. This program was created 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 continued access to high quality DMEPOS items and services, bring Medicare's DMEPOS payments in line with current market pricing, and help combat supplier fraud. In addition, the program is expected to result in billions of dollars of taxpayer and beneficiary savings.

Overview

CMS is the largest purchaser of health care in the United States, serving more than 100 million Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. In Fiscal Year 2009, Medicare covered 46.3 million individuals with total program expenditures exceeding $500 billion. Medicare spent approximately $8.1 billion on DMEPOS alone in 2009, providing DMEPOS to 10.6 million beneficiaries. Each year, DMEPOS suppliers provide items and services including power wheelchairs, oxygen equipment, walkers and hospital beds to millions of Medicare beneficiaries.

The current Medicare fee-for-service DMEPOS benefit is plagued by an obsolete pricing methodology, grossly inflated prices, and a well-documented proliferation of fraudulent

practices. Medicare currently pays for DMEPOS items and services using fee schedule rates for covered items. In general, fee schedule rates are calculated using historical supplier charge data from approximately 25 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 furnished to non-Medicare customers. Medicare beneficiaries and taxpayers bear the cost of these inflated fee schedule rates. The Administration believes that competitive bidding for DMEPOS will help put an end to Medicare beneficiaries and the Medicare Part B trust fund being overcharged for these items and services. Table 1 shows the difference between the current CMS payment rates for certain DMEPOS items compared to current prices a consumer would see if shopping for that item on the Internet.

Table 1: Illustrative Comparison Prices Pre-Competitive Bidding

DMEPOS Items	*CMS payment based on fee schedule amount*	*Illustrative Internet Price*[1]
Standard power mobility device	$3,641	$1,300
Folding walker	$101	$40
Continuous positive airway pressure device	$1,000[2]	$399

[1] Prices obtained from Internet on September 3, 2010.

[2] Price is the sum of rental payments for 13 months of use after which the beneficiary takes over ownership of the equipment.

The Department of Health and Human Services' Office of Inspector General (OIG), the Government Accountability Office (GAO), and other independent analysts have repeatedly highlighted that the current fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or cash customers. These inflated prices in turn increase the amount beneficiaries must pay out-of-pocket for these items. DMEPOS competitive bidding will bring Medicare payments

for DMEPOS more in line with market prices while protecting beneficiaries' access to reputable suppliers.

Background

The DMEPOS competitive bidding program is an essential tool that will help CMS realign Medicare's pricing to pay appropriately for DMEPOS items and services. This tool was proven effective in successful competitive bidding demonstrations in Polk County, Florida and San Antonio, Texas between 1999 and 2002. The demonstrations resulted in 20 percent savings for Medicare and beneficiaries and unchanged access to equipment and quality for beneficiaries. In addition, beneficiaries had overall high satisfaction with the service from these competitive bidding demonstration suppliers. Since the 2002 demonstration, Congress has enacted a number of additional modifications to the DMEPOS competitive bidding program to improve the program and enhance program oversight and monitoring.

The Medicare DMEPOS Competitive Bidding Program was established by the MMA after the conclusion of the successful demonstration projects. Under the MMA, DMEPOS Competitive Bidding Programs were to be phased into Medicare so that competition under the program would occur in 10 metropolitan statistical areas (MSAs) in 2007. Consistent with the statutory mandate, CMS conducted the Round 1 competition in 10 areas and for 10 DMEPOS product categories, and implemented the program on July 1, 2008, for two weeks. The program's single payment amounts resulted in a projected savings of approximately 26 percent compared to the traditional Medicare fee schedule. This indicated the potential for substantial savings for Medicare beneficiaries and taxpayers upon full scale implementation of the program.

On July 15, 2008, MIPPA terminated the Round 1 contracts that were in effect and reinstated fee schedule payment rates; delayed the program; required rebidding of the first round at a later date; and required a 9.5% reduction and no update for Round 1 items for all areas in 2009. MIPPA required competition for Round 2 of the program to be conducted in 2011 in 70 additional MSAs. In addition to the delay, MIPPA mandated certain limited changes but did not change the fundamental nature of the competitive bidding program. For example, MIPPA established a "covered document" review process for providing feedback to suppliers regarding missing

financial documents and a requirement for contract suppliers to disclose their subcontractors to CMS. MIPPA also excluded certain DMEPOS items and areas from competitive bidding and provided an exemption to the program for certain providers and suppliers. Finally, MIPPA extended the duration of the Program Advisory and Oversight Committee (PAOC), which advises the Secretary on a number of issues related to implementation of the competitive bidding program. The PAOC includes representatives of beneficiaries, physicians and other practitioners, suppliers, States, organizations that help to establish professional standards, financial standards experts, and representatives from industry associations.

The Affordable Care Act of 2010 expands the number of Round 2 MSAs from 70 to 91 and mandates that all areas of the country are subject either to DMEPOS competitive bidding or payment rate adjustments using competitively bid rates by 2016.

The DMEPOS competitive bidding program replaces the existing outdated, excessive fee schedule amounts with market-based prices. Under the program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. The new, lower payment amounts resulting from the competition will replace the fee schedule amounts for the bid items in these areas. The payment amounts for the first phase of the program are projected to result in average savings of 32 percent as compared to the current fee schedule prices. These new payment amounts are scheduled to go into effect on January 1, 2011 in nine areas of the country. The program is expected to save more than $17 billion over ten years (FY2011 – FY2020) as CMS phases in the program as mandated by MIPPA and the Affordable Care Act. In addition to this positive impact on the Medicare Part B trust fund balance, the program is expected to save beneficiaries more than $11 billion over the next ten years as a result of lower coinsurance payments and lower monthly premium payments. The overall combined savings to Medicare and beneficiaries is therefore expected to total more than $28 billion over the first ten years of the program -- without compromising quality or access.

It is important to note that savings for the Medicare trust fund, beneficiaries, and taxpayers will not come at the expense of quality items and services or beneficiary access. The DMEPOS competitive bidding program provides important safeguards to ensure participation of only qualified suppliers, continued customer service and access to high quality DMEPOS for beneficiaries, as well as improved oversight protections against fraud. These safeguards are expected to increase the quality of DMEPOS products and services furnished to beneficiaries, while protecting beneficiaries and taxpayers from fraudulent or unscrupulous providers.

The increased oversight and monitoring of DMEPOS suppliers ensures that winning suppliers meet specific quality and financial standards including accreditation of all bidders by an independent accrediting organization. These independent accrediting organizations must examine compliance with business standards and product safety standards, including product-specific service and quality standards. Business standards include how the company is run, how finances and staff performance are managed, how well the company takes care of its consumers, the safety of their products and whether the company's information management systems are in place. Product-specific service standards include intake, delivery and setup, training and instruction of the beneficiary and/or their caregiver and follow-up service. In addition, during the bid selection process, a suppliers' financial health is evaluated through the review of tax and financial documents, and full compliance with appropriate State licensure is also verified. Further, by bringing Medicare prices more in line with the prices of other payers, the competitive bidding program will also make such items and supplies a less profitable target area for fraudsters and bad actors.

Implementation of the Round 1 Rebid

As required by MIPPA, CMS conducted the second Round 1 competition (known as the Round 1 Rebid) in 2009. MIPPA requires that the Round 1 Rebid be conducted in the same areas as the 2008 Round 1 competition, with the exception of Puerto Rico, which was explicitly excluded by MIPPA.

These areas are:

- Charlotte – Gastonia – Concord (North Carolina and South Carolina)
- Cincinnati – Middletown (Ohio, Kentucky and Indiana)
- Cleveland – Elyria – Mentor (Ohio)
- Dallas – Fort Worth – Arlington (Texas)
- Kansas City (Missouri and Kansas)
- Miami – Fort Lauderdale – Pompano Beach (Florida)
- Orlando – Kissimmee (Florida)
- Pittsburgh (Pennsylvania)
- Riverside – San Bernardino – Ontario (California)

MIPPA designated the items that are included in the Round 1 Rebid. Specifically, MIPPA required CMS to re-compete the same items and services that were bid in the initial Round 1 with certain limited exceptions. Negative pressure wound therapy (NPWT) items and services are excluded from the Round 1 Rebid, but may be included in subsequent rounds. However, Group 3 complex rehabilitative power wheelchairs are excluded from the entire competitive bidding program.

Therefore, the Round 1 Rebid includes the following categories of items and services:

- Oxygen, Oxygen Equipment, and Supplies
- Standard Power Wheelchairs, Scooters, and Related Accessories
- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2 only)
- Mail-Order Diabetic Supplies
- Enteral Nutrients, Equipment and Supplies
- Continuous Positive Airway Pressure (CPAP) Devices, Respiratory Assist Devices (RADs), and Related Supplies and Accessories
- Hospital Beds and Related Accessories
- Walkers and Related Accessories
- Support Surfaces (Group 2 mattresses and overlays in Miami-Ft.-Lauderdale-Pompano Beach, FL only)

Key Operational Improvements

In implementing the Round 1 Rebid, CMS has incorporated all of the program improvements required by MIPPA. In addition, CMS implemented a number of other important improvements based on our evaluation of the 2008 bidding process, feedback from stakeholders, and advice from the PAOC received through two public meetings and three additional conference calls. Some examples of these key operational improvements include an upgraded bidder education program completed prior to the opening of the bid window, a new and improved online bidding system, an enhanced bid evaluation processes such as a comprehensive upfront licensing verification process, a more rigorous bona fide bid evaluation process, and increased scrutiny of expansion plans for suppliers new to an area or product category.

Supplier Communication and Education

CMS provided many educational tools for the rollout of Round 1, but conducted much of the education concurrent with bidding. Stakeholders and the PAOC gave us feedback that additional education and outreach needed to occur earlier in the process. Consistent with that feedback, CMS began the Round 1 Rebid education campaign in May of 2009 with general "pre-bidding" supplier awareness and education efforts on key steps suppliers were required to take in order to be ready for registration and bidding, including getting appropriate State licenses, updating their Medicare enrollment files with the National Supplier Clearinghouse, and getting accredited and bonded.

After the pre-bidding awareness campaign, CMS launched an intensive bidder education campaign designed to ensure that DMEPOS suppliers interested in bidding had all the information they needed to submit a complete bid in a timely manner. CMS held eight bidders' conferences, during which all parts of the bidding process were explained to suppliers; these bidders' conferences were held via teleconference to maximize supplier participation. CMS' Competitive Bidding Implementation Contractor (CBIC) maintained a dedicated website which included a comprehensive array of important information for suppliers, including bidding rules, user guides, frequently asked questions, policy fact sheets, checklists, and bidding information charts. The CBIC also maintained a toll-free help desk and sent listserv announcements in order to disseminate key information about registration and bidding to suppliers. CMS concluded the

intensive phase of the bidder education campaign before the bid window opened, and continued to offer support to bidding suppliers during the entire bidding period.

Online Bidding System

The online bid submission system used in the original Round 1 had numerous technical issues that caused difficulties for bidders. In response to these issues, before the launch of the Round 1 Rebid, CMS developed a new and improved online system called the DMEPOS Bidding System (DBidS). The DBidS system, which included user-friendly functionality such as a "cut and paste" feature, operated properly throughout the bidding window.

Bid Evaluation Process

CMS instituted a number of critical improvements to the supplier selection process for the Round 1 Rebid. These improvements to the supplier and bid review process will provide additional protection for beneficiaries and help to prevent fraudulent suppliers from receiving contracts.

Quality Standards: The MMA required the Secretary to establish quality standards for all DMEPOS suppliers to be applied by independent accreditation organizations but did not set a date by which all suppliers must be accredited. MIPPA clarified that all suppliers must be accredited by October 1, 2009. The DMEPOS quality standards address the set-up and delivery of items and services, beneficiary education on the use of these products, and the accountability, business integrity, and performance management of suppliers. In addition to the general quality standards that all suppliers must meet, there are also product-specific standards for certain items that suppliers must meet in order to furnish these items. For example, suppliers of respiratory equipment such as oxygen equipment, respiratory assistance devices and continuous positive airway pressure devices must comply with specific American Association for Respiratory Care practice guidelines. Another example of product-specific quality standards currently in place is the requirement that every location operated by a supplier of Group 2 complex rehabilitative power wheelchairs employ at least one qualified rehab technology supplier, or be certified as a rehab technology supplier.

As in the initial Round 1, CMS verified bidder accreditation status directly with the accreditation organizations, and only properly accredited suppliers were offered contracts. In the Round 1 Rebid, contract suppliers must also meet MIPPA-mandated requirements to disclose their subcontractors and submit proof of accreditation when applicable. Subcontractors must also meet the same accreditation standards required by principal contract suppliers in order to furnish DMEPOS to Medicare beneficiaries.

Financial Standards: The MMA also required that suppliers meet financial standards established by the Secretary in order to contract with Medicare under the competitive bidding program. The competitive bidding regulations established prior to the initial Round 1 require financial standards to be set forth in the request for bids (RFB). These financial standards allow CMS to assess the capability of suppliers to provide quality items and services in sufficient quantities to meet beneficiaries' needs and help screen out fraudulent suppliers with no financial history (e.g., credit or tax history). As part of the bid solicitation process, each supplier submitted required financial documentation, including balance sheets, statements of cash flow, and tax return extracts. CMS evaluated each bidder's financial documentation to determine whether the supplier had met the standards required to participate in the program and to support each bidder's claims of their supply capacity.

In the initial Round 1, suppliers were required to submit three years of financial documents. Based on experience from the initial Round 1, CMS determined that bidders' financial health could be adequately measured through fewer years of documents. Therefore, CMS streamlined the submission requirements for the Round 1 Rebid RFB, to require suppliers to submit one year of financial documents.

"Covered Document" Review: In the initial Round 1, many bidders were disqualified because they did not submit all required financial documents specified in the Request for Bids. In response to these concerns, MIPPA required a special document review process for all future rounds of the program. Under this process, suppliers that submit their financial documents by a deadline called the Covered Document Review Date (CDRD) had their documents checked to determine if any financial documents were missing. Bidders that took advantage of this process

were notified of what was missing and were provided an opportunity to submit these documents. MIPPA mandated that this process would apply only to determination of missing financial documents and not to the accuracy or completeness of individual documents. 791 suppliers took advantage of the covered document review process. 321 of the 791 suppliers that submitted a financial document by the CDRD were missing at least one document and were notified of what was missing. All but 14 of the suppliers notified submitted all of the required documentation.

Licensure Review: In the initial Round 1, bidders were required to meet all State licensure requirements prior to submitting a bid. However, there were concerns that some of the 2008 contract suppliers did not have all required licenses. To address this issue for the Round 1 Rebid, CMS instituted a rigorous, comprehensive verification of bidder's compliance with all applicable State licensure requirements early in the bid evaluation process. This involved checking supplier licenses already on file with Medicare, working directly with States to confirm the licensure status of specific bidders, and working directly with suppliers when necessary to verify that they meet the licensure requirements. Further, CMS only offered contracts to suppliers that were properly licensed in each State and for each particular service that the suppliers applied for at the time of their bid application.

Bona Fide Bids: Under the DMEPOS competitive bidding program, only suppliers that submitted bona fide bids can be awarded contracts. Accordingly, all bids submitted under the Round 1 Rebid were screened to ensure that they represent a rational, sustainable, and feasible payment for furnishing the item. In instances where a bid was identified through the bona fide bid screening process as extremely low in relation to other bids, CMS further evaluated that bid to confirm that the supplier could furnish the item at the listed bid amount. In so doing, we reviewed additional information beyond that collected in 2008, such as supplier rationales that support documentation like manufacturer's invoices. During the course of evaluating low bids to ensure that they are bona fide, we obtained numerous invoice prices from current suppliers of these items that are significantly lower than current Medicare fee schedule amounts and internet retail prices. These invoice prices clearly demonstrate that the Medicare fee schedule amounts are excessive and that all bids used in calculating the single payment amounts are bona fide, sustainable, and established in accordance with the goal of the program, which is to establish

reasonable payment amounts for quality items and services under the Medicare program. Only "bona fide" bids were considered for contracts and included in the calculation of the single payment amounts.

Capacity and Expansion Plans: CMS improved its capacity and expansion plan review for the Round 1 Rebid after consultation with the PAOC. The PAOC raised initial concerns that bidders new to an area or product category or reporting high capacity figures might not be able to ramp up to their reported capacity in time to meet the projected demand at the beginning of the contract period.

To address these concerns, CMS utilized a "capacity ramp up" analysis to review what percentage of demand in 2011 would be met by experienced suppliers reporting a modest expansion in capacity and what percentage of demand in 2011 would be met by new suppliers or experienced suppliers reporting more than a modest expansion in capacity. In any case where this second category of suppliers was counted on to meet any portion of projected demand in 2011, the expansion plans of these suppliers were scrutinized with particular emphasis on liquid assets and available credit needed to expand capacity. If a supplier's expansion plan did not substantiate the supplier's estimated capacity, CMS adjusted the capacity of the supplier to the supplier's historic level for the purpose of selecting enough contract suppliers to meet expected demand. Further, in order to ensure appropriate capacity planning and market competition between DMEPOS suppliers in each area, CMS did not allow any one supplier to account for more than 20 percent of the market. Finally, it is important to note that CMS' projected demand calculations for rented items of DME in 2011 is not discounted in any way to account for the items that will be furnished by non-contract, grandfathered suppliers. In order to ensure sufficient capacity to serve all beneficiary needs, contract supplier capacity was reviewed as if 100 percent of demand must be met by the winning suppliers.

Beneficiary Protections

Consistent with past competitive bidding demonstrations, we fully 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 accreditation requirements. 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. For example, all suppliers of oxygen and oxygen equipment are accredited to ensure that they provide respiratory services 24 hours a day, 7 days a week, as needed by the beneficiary.

- 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 based on quality and customer service among winning suppliers will provide beneficiaries with choices regarding 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 beneficiary-owned equipment from any DMEPOS supplier with a valid Medicare billing number, regardless of whether or not the supplier is a contract supplier.

- 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. In other words, contract suppliers cannot discriminate against Medicare beneficiaries and must treat them as they do other individuals needing DMEPOS. For transparency, we will post on our Web site a list of brands furnished by each contract supplier.

- In order to protect beneficiaries from financial liabilities, beneficiaries will not be financially liable when a non-contract supplier furnishes them with a competitively bid item unless they have signed an Advance Beneficiary Notice (ABN).

Small Supplier Protections

While implementing the DMEPOS competitive bidding program, CMS worked closely with suppliers, manufacturers, and beneficiaries through a transparent and open 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 industry representatives and stakeholders. As a result, CMS' policies and implementation of the Round 1 Rebid pay close attention to the concerns of these constituencies, in particular those of small suppliers.

During the implementation of the initial 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 defined as a supplier that generates gross revenues of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue, instead of 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.

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

As a result of CMS' efforts to give special consideration to small suppliers, 48 percent of the suppliers offered Round 1 Rebid contracts on July 1, 2010 are small suppliers.

Round 1 Rebid Results

As part of the Round 1 Rebid, CMS received 6,215 complete bids from 1,011 suppliers. Utilizing the rigorous review process described above, each bidder and bid was systematically vetted and verified before CMS began offering contracts to these suppliers. On July 1, 2010, CMS made early 1,300 contract offers to 364 suppliers. These suppliers have 622 locations to serve Medicare beneficiaries in the nine competitive bidding areas. 72 percent of these suppliers currently furnish contract items in the area. If any contract offers are not accepted, CMS will offer contracts to other bidders as needed to meet beneficiary demand and anticipated capacity needs.

The single payment amounts for the Round 1 Rebid, which were calculated based on bids submitted by suppliers, were announced on July 1, 2010. As a result of the competitive bidding process, the amounts that Medicare will pay for the nine product categories included in the Round 1 Rebid are 32 percent less on average than Medicare's current fee schedule amounts. In addition to lower Medicare payments, this directly translates to reduced beneficiary out-of-pocket expenses for certain medical equipment and supplies. The following are examples of savings for three commonly used items: an oxygen concentrator; a semi-electric hospital bed; and a typical monthly supply of 100 diabetic test strips and 100 lancets.

Table 2: Illustrative Comparison Prices Post-Competitive Bidding

Item/Period of Service	Current Fee Schedule Allowed Amount**	New Single Payment Amount, under Competitive Bidding**	Medicare Savings 80% of Difference	Beneficiary Copayment Savings 20% of Difference***	Total Savings
Concentrator					
Per month	$173.17	$116.16	$45.61	$11.40	-32.9%
Per year	$2,078.04	$1,393.95	$547.27	$136.82	-32.9%
Per 3 years	$6,234.12	$4,181.84	$1,641.82	$410.46	-32.9%
Hospital Bed					
Per month	$127.12	$80.35	$37.42	$9.35	-36.7%
Per 13 months*	$1,334.76	$843.63	$392.91	$98.23	-36.8%
Diabetic Supplies					
Per month	$75.32	$33.44	$33.51	$8.38	-55.6%
Per year	$903.87	$401.24	$402.10	$100.53	-55.6%
Per 3 years	$2,711.60	$1,203.72	$1,206.30	$301.58	-55.6%

* Beneficiary takes over ownership of equipment after end of rental payment period.

** 20% of current fee schedule and new allowed amount is paid by the beneficiary out-of-pocket, after they have reached their Part B deductible.

***Beneficiaries will also benefit from lower Medicare Part B premiums in addition to copayment savings.

CMS is currently in the process of finalizing contracts with participating suppliers, and hopes to announce the contract suppliers in the coming weeks. CMS will send letters to all suppliers that have not been offered contracts explaining why they were not awarded a contract and give them an opportunity to ask questions and express concerns. The contract suppliers will begin furnishing beneficiaries with DMEPOS at the single payment amount on January 1, 2011.

CMS continues to analyze the impact of the competitive bidding program on suppliers that may not become contract suppliers. As context, although a large number of DMEPOS suppliers are enrolled in Medicare to furnish DMEPOS items, only about 20 percent of the suppliers in the nine Round 1 Rebid areas conduct a significant amount of Medicare business (e.g., had more

than $10,000 in allowed charges in 2009), and only 11 percent of suppliers in the nine Round 1 Rebid areas submitted more than $50,000 in allowed charges in 2009.

In many cases, suppliers that are not offered a contract will still be able to provide certain services to beneficiaries by subcontracting with an approved contract supplier or may become grandfathered suppliers that continue to furnish oxygen and oxygen equipment or rented durable medical equipment to their current customers. Most suppliers elected to continue as grandfathered suppliers under the demonstrations, and approximately 90 percent of suppliers planned to continue furnishing oxygen and oxygen equipment as grandfathered suppliers under the initial Round 1 in 2008. Based on this experience, we expect a high percentage of suppliers will elect to become grandfathered suppliers and continue serving their current patients.

Outreach and Education

Outreach and education of beneficiaries and stakeholders is a key priority for CMS as we prepare to implement the DMEPOS competitive bidding program on January 1, 2011. A comprehensive outreach and education plan is under development to educate beneficiaries, beneficiary partners, providers, stakeholders and contract suppliers. CMS is committed to ensuring that all beneficiaries have the information they need in a timely manner to maintain access to necessary products and services. The primary goal of this education campaign will be to keep beneficiaries, caregivers, referral agents (e.g., hospital discharge planners and physicians), and other stakeholders informed about the new program and how it affects them. Outreach to beneficiaries will include fact sheets, brochures and booklets, Frequently Asked Questions and other postings on medicare.gov, newsletters, an update to the annual *Medicare & You Handbook*, emails, and letters. In addition, our 1-800-MEDICARE customer service representatives and direct service caseworkers are being trained and educated so they are better able to assist beneficiaries who may come to them with questions about the program.

CMS will work with providers of health care services, established networks of providers, and beneficiary advocacy organization partners to keep beneficiaries informed. Outreach to physicians, social workers, referral agents, discharge planners and others will be delivered through the various listservs, and through the Medicare Learning Network (MLN), via MLN Matters articles, fact sheets, brochures, and national provider calls. Educational materials for

medical professionals will be available on the cms.gov website and are also communicated through national and state/local provider associations covering all provider types, as well as through the Medicare fee-for-service contractors via their websites, listservs, bulletins and educational seminars. Local outreach in the nine competitively bid areas (CBA) is already underway to educate health care providers, particularly those who refer beneficiaries to suppliers of the DMEPOS items included in the program.

CMS also plans a special education program for contract suppliers to ensure that they understand all of their obligations. Contract supplier educational materials will be posted on the CBIC website and will include fact sheets, FAQs, and other materials. CMS will hold educational sessions for contract suppliers via teleconference and transmit key information via listservs.

Program Oversight and Monitoring

In order to ensure that beneficiaries' DMEPOS needs are satisfactorily met, CMS will be proactively monitoring the implementation of the competitive bidding program through numerous methods.

Beneficiary Surveys

We will be actively seeking feedback from beneficiaries through consumer satisfaction surveys conducted before and after the rollout of the program. These surveys will provide direct insight into how the program is affecting beneficiaries. In addition to these surveys, 1-800-MEDICARE is prepared to field questions and concerns from beneficiaries. CMS is committed to quickly addressing all comments and concerns from beneficiaries and will work with our regional offices to respond, and investigate when appropriate, as quickly as possible.

Competitive Acquisition Ombudsman

As required by MIPPA, CMS appointed an Acting Competitive Acquisition Ombudsman (CAO) in July 2009 to respond to inquiries and complaints from suppliers and individuals regarding the application of the program. The CAO's core functions include: ensuring appropriate processes for handling supplier and beneficiary complaints and inquiries; an annual report to Congress; identifying potential issues and developing risk mitigation strategies with CMS, and

communicating identified concerns of beneficiaries and suppliers to CMS. The CAO will begin to hear complaints after contract suppliers are announced.

To date, the CAO has established Ombudsman operations and business processes and has been meeting with key stakeholders, such as the PAOC, disability advocates, and partners to identify potential issues. The CAO will play an important role during the implementation of the competitive bidding program by assisting suppliers and beneficiaries with their complaints, reporting on potential service and quality concerns, and working with the Agency and partners to respond to these complaints and concerns.

Complaint Process

When competitive bidding is implemented in 2011, there will also be a formal complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract supplier or other competitive bidding implementation issues. This process is designed to ensure that all complaints are correctly routed, investigated, resolved, tracked and reported.

Quarterly Report

Contract suppliers will be required, as a term of their contract, to fill out a quarterly report on the specific brands of items they furnish to Medicare beneficiaries. The information on this report will be used to update the supplier locator tool on the medicare.gov website so that beneficiaries and caregivers are able to easily identify contract suppliers that offer the brands they need. This quarterly report will also help CMS evaluate supplier compliance with the non-discrimination contract requirement, which requires contract suppliers to make the same items available to Medicare and non-Medicare customers.

Local Outreach

The CMS regional offices and local CBIC ombudsmen will provide on-the-ground presence in each competitive bidding area. They will closely monitor transition activities, conduct environmental scanning, analyze trends, and identify and address any emerging issues. These efforts will inform the agency on potential issues, vulnerabilities and readiness for effective and credible management of the program.

Claims Analysis

Claims analysis is the final piece of our comprehensive oversight and monitoring plan. Through more sophisticated claims analysis, CMS will be able to identify utilization trends, monitor beneficiary access, address aberrancies in services, and target potential fraud and abuse.

Future Rounds of DMEPOS Competitive Bidding

CMS has shared its preliminary timeline for phase-in of Round 2 of the program with the PAOC and expects contracts and payment amounts for this Round to take effect on January 1, 2013, following the competition which is mandated to occur in 2011 in accordance with MIPPA. Due to changes authorized by the Affordable Care Act, Round 2 of competitive bidding will expand the program to include 91 additional MSAs, bringing the total competitive bidding MSAs to 100. National mail order for diabetic testing supplies can also be implemented after 2010. CMS has recently published a proposed rule (CMS-1503-P) on the implementation of the national mail order program as well as policies affecting Round 2. The rule is expected to be finalized later this year in order to meet the requirements of the statute to phase-in the Round 2 competition in 2011 and any competitions for national mail order items and services after 2010.

Conclusion

Past experience has shown that competitive bidding of DMEPOS products and services can provide savings, value, and benefits to both beneficiaries and the Medicare program, while ensuring delivery of quality items and services. CMS understands the concerns of Congress and stakeholders, and in the Round 1 Rebid, has taken care to improve and implement the program in a way that emphasizes the needs of beneficiaries while addressing the concerns of suppliers. In the coming months, CMS will continue to implement the DMEPOS Round 1 Rebid and future competitive bidding program rounds in an open and orderly way.

Mr. PALLONE. Thank you, Mr. Wilson.
Mr. Levinson.

STATEMENT OF DANIEL LEVINSON

Mr. LEVINSON. Good afternoon, Chairman Pallone, Mr. Whitfield and members of the subcommittee. Thank you for the opportunity to discuss the integrity of Medicare's coverage of durable medical equipment and supplies, or DME.

Medicare pays for DME on behalf of more than 11 million beneficiaries at a cost of more than $10 billion a year. In 2009, CMS estimated that more than half of DME claims were paid in error.

The vast majority of Medicare suppliers are honest and well intentioned. However, even a small minority of unscrupulous suppliers drains Medicare funds and puts beneficiaries at risk. OIG's work has demonstrated that this benefit is particularly vulnerable to fraud, waste and abuse. My testimony focuses on two key vulnerabilities described more fully in my written statement. These are the ease with which fraudulent suppliers obtain billing privileges and DME payment rates that exceed market prices.

Although DME accounts for just 2 percent of Medicare spending, approximately 14 percent of OIG's health care fraud investigations involve DME. These investigations have found that criminals set up sham DME storefronts and fraudulently bill Medicare for millions of dollars. Then they close up shop and reopen in a new location under a new name and repeat the fraud. Entry into the DME business has been too easy, and oversight and enforcement of Medicare enrollment standards has been weak. For example, almost one-third of the 1,600 DME suppliers billing Medicare in south Florida did not have an open and staffed physical location when OIG conducted site visits.

In addition, Medicaid frequently reimburses for DME federal rate above acquisition costs resulting in waste and increased beneficiary copayments and making fraudulent billing more lucrative. For example, in 2007, OIG found that Medicare reimbursed suppliers for wound therapy pumps based on a purchase price of more than $17,000. However, suppliers paid approximately $3,600 for new models of these pumps. Likewise, in 2007 Medicare paid about $4,000 for standards power wheelchairs that cost suppliers about $1,000 to acquire. Our investigations have demonstrated that pricing disparities make DME a lucrative target for criminals. In numerous cases, criminals have supplied unneeded power wheelchairs and scooters to beneficiaries because the Medicare payment is excessive enough to make this scam profitable.

The profitability of DME fraud has given rise to increasingly sophisticated schemes and more violent perpetrators. For example, in southern California, an individual established numerous sham DME companies using street gang members to pose as owners. These sham suppliers enrolled in Medicare and submitted millions of dollars in fraudulent claims for power wheelchairs and orthotic devices. The gang members involved had previously been convicted of charges ranging from assault to narcotics violations.

In response, we are taking strong action to protect the integrity of the Medicare DME benefit. Innovative uses of information technology and data analysis have dramatically enhanced the govern-

ment's ability to detect, prevent and respond to fraud. OIG analyses data to identify fraud hotspots and to alert CMS to potential fraud so that it can implement appropriate program safeguards.

OIG and the Department of Justice are accelerating the government's response to fraud schemes. Medicare fraud Strike Force can quickly detect, investigate and prosecute fraud before the criminals and stolen funds disappear. The Strike Force teams combine data analysis with field intelligence to crack down on sham DME suppliers and other fraud perpetrators. Our teams are working to stay ahead of the criminals as their fraud schemes replicate and migrate.

CMS has taken some important steps such as requiring accreditation and surety bonds to strengthen provider enrollment standards. The Affordable Care Act requires CMS to conduct more stringent risk-based provider enrollment screening.

The Medicare competitive bidding program holds promise to address payment vulnerabilities by better aligning DME reimbursement with market prices. It also provides a mechanism for ensuring that CMS has better information about suppliers when granting billing privileges. If policymakers consider a different course, it remains imperative to take prompt, appropriate action to ensure the integrity of the benefit. My office remains committed to monitoring program integrity and beneficiary access to reasonably priced, medically necessary, quality medical equipment and supplies.

In conclusion, I appreciate and share your commitment to fighting DME fraud, waste and abuse and I welcome your questions.

[The prepared statement of Mr. Levinson follows:]

Testimony before the United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

"Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access"

Testimony of:

Daniel R. Levinson
Inspector General
U.S. Department of Health & Human Services

September 15, 2010
10:00AM
2123 Rayburn House Office Building

Testimony of:
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Good morning, Chairmen Waxman and Pallone, Ranking Members Barton and Shimkus, and distinguished Members of the Subcommittee. I am Daniel Levinson, Inspector General of the U.S. Department of Health & Human Services. I thank you for the opportunity to appear before you today to discuss the Office of Inspector General's (OIG) efforts to combat health care fraud, waste, and abuse, specifically as it relates to medical equipment and supplies.

My testimony today will focus on OIG's body of work and recommendations related to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Over the past three decades, OIG has identified significant levels of fraud and abuse related to this important Medicare benefit. I will describe OIG's strategy for strengthening the integrity of the health care system in the context of the five principles OIG has identified as essential to combating health care fraud. I also will discuss recent improvements to ensure the integrity of the DMEPOS benefit. Finally, I will discuss additional corrective action needed to ensure that necessary DMEPOS are provided to beneficiaries appropriately, efficiently, and without fraud.

OIG's five-principle strategy combats health care fraud, waste, and abuse

Fraud, waste, and abuse in the Medicare and Medicaid programs cost taxpayers billions of dollars each year and put beneficiaries' health and welfare at risk. The impact of these losses and risks is exacerbated by the growing number of people served by these programs and the increased strain on Federal and State budgets. Therefore, it remains critical that oversight of these essential health care programs be strengthened. To combat health care fraud, a comprehensive strategy of prevention, detection, and enforcement is required. To that end, OIG has identified five principles of an effective health care integrity strategy:

1. Enrollment: Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment or reenrollment in the health care programs.
2. Payment: Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice.
3. Compliance: Assist health care providers and suppliers in adopting practices that promote compliance with program requirements.
4. Oversight: Vigilantly monitor the programs for evidence of fraud, waste, and abuse.
5. Response: Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.

No Medicare benefit area underscores the importance of these principles more than durable medical equipment and supplies. With respect to the first principle, enrollment, we have found that low barriers to entry and weak oversight and enforcement of enrollment standards make DMEPOS a compelling target for fraudulent suppliers. It is easy to become a DMEPOS supplier, relative to other types of providers, such as physician practices and hospitals, which

require extensive licensure and credentialing. In many geographic areas, DMEPOS suppliers are abundant. Regarding the second principle, payment, OIG reviews have consistently revealed that Medicare reimbursement rates for certain DMEPOS are significantly misaligned with market prices. This makes DMEPOS fraud particularly lucrative, further attracting bad actors to the system. These problems must be addressed to safeguard the Medicare Trust Fund from fraud and abuse.

These vulnerabilities can be offset through efforts to implement the final three principles: compliance, oversight, and response. For OIG's part, we strive to educate and provide assistance to the many legitimate suppliers that seek to comply with Medicare laws and regulations. We conduct oversight reviews of the DMEPOS benefit to identify fraud, waste, and abuse and recommend actions to the Centers for Medicare & Medicaid Services (CMS) to better safeguard the integrity of the program. Finally, in partnership with the Department of Justice (DOJ), we work to ensure that once detected, fraud schemes are shut down and perpetrators are prosecuted.

Medicare provides DMEPOS to more than 11 million beneficiaries, at a cost of more than $10 billion per year

To provide context, I will first offer some background about the Medicare DMEPOS benefit.

Medicare Part B provides for coverage of DMEPOS if the equipment is necessary and reasonable for treatment of an illness or injury or to improve the functioning of a malformed body member. Durable medical equipment (DME) is defined as equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. DME includes items such as oxygen equipment, wheelchairs, nebulizers, walkers, and other equipment that physicians prescribe for home use. Prosthetic devices are devices needed to replace a body part or function, such as artificial limbs and cardiac pacemakers. Orthotic devices include leg, arm, back, and neck braces that provide rigid or semirigid support to weak or deformed body parts or restrict or eliminate motion in a diseased or injured part of the body. Medicare-reimbursed supplies are items that are used in conjunction with DME, such as drugs used for inhalation therapy, or are items that need to be replaced on a frequent (usually daily) basis, such as surgical dressings.

Medicare pays for DMEPOS through fee schedules. These fee schedules are based on the average amount that suppliers charged on Medicare claims in 1986 for individual DMEPOS items and are adjusted for inflation. Medicare pays 80 percent of the cost of a DMEPOS item up to the fee schedule amount, while the beneficiary is responsible for paying the remaining 20 percent.

Medicare pays for DMEPOS claims on behalf of more than 11 million beneficiaries. In 2009, Medicare payments for DMEPOS exceeded $10 billion and represented approximately 2 percent of all Medicare expenditures for that year.[1] In 2009, nearly 100,000 DMEPOS suppliers were enrolled in Medicare.

[1] See "Improper Medicare FFS Payments Report November 2009," available at http://www.cms.gov/CERT/Downloads/CERT_Report.pdf.

To be eligible for Medicare reimbursement, all DMEPOS suppliers must enroll in the program and must comply with 26 supplier standards. These standards are designed to ensure that suppliers are legitimate. Standards include but are not limited to the following:

- The supplier must maintain a physical facility.
- The facility must be accessible during business hours.
- The facility must have a visible sign.
- The supplier's hours of operation must be posted.
- The supplier must maintain a primary business telephone listed under the name of the business.

The National Supplier Clearinghouse (NSC), under contract with CMS, is responsible for verifying initial and ongoing compliance with the 26 supplier standards and issuing Medicare billing numbers to DMEPOS suppliers. Also, DMEPOS suppliers must be accredited prior to submitting applications and must renew their applications every 3 years. For most suppliers, NSC conducts an unannounced site visit before approving applicants and granting Medicare billing privileges. NSC may also conduct an unannounced reenrollment site visit every 3 years. Site visits may take place at any other time as deemed necessary, but generally site visits are made only when suppliers enroll and reenroll in the Medicare program.

To participate in the Medicare DMEPOS Competitive Bidding Program, DMEPOS suppliers must continue to meet the 26 supplier enrollment standards, which also include being accredited by a CMS-approved accreditation organization, fulfilling all licensing requirements, and obtaining a surety bond.

Enrollment: It has been too easy for fraudulent DMEPOS suppliers to obtain Medicare billing privileges

The enrollment standards that I have described are intended to ensure that only legitimate and qualified businesses are enrolled as Medicare suppliers. Unfortunately, we have found that all too often, unscrupulous suppliers are able to gain entry to the system and defraud Medicare. For example, in southern California, an individual defrauded the Medicare program by establishing various fraudulent DMEPOS companies, primarily by using street gang members to pose as nominee owners of his sham companies. He paid each gang member $5,000 to establish bank accounts and to fill out the Medicare paperwork. The nominee owners submitted claims for reimbursement to Medicare for power wheelchairs and orthotic devices that were not medically necessary or legitimately prescribed by a physician. To date, nine of the gang members and associates have been indicted for charges including health care fraud and providing false statements to Government agencies. The gang members involved in this fraud had previously been convicted of charges ranging from assault on a peace officer to numerous narcotics violations. Thus far in fiscal year 2010, OIG investigations of DMEPOS fraud have resulted in more than 80 convictions with ordered recoveries of more than $90 million.

OIG has identified systemic enrollment vulnerabilities for more than a decade. Since 1997, OIG has issued several reports that have assessed supplier compliance with standards by conducting unannounced site visits. We have consistently found that Medicare enrollment standards and

oversight are not sufficient to prevent noncompliant and sham suppliers from obtaining Medicare provider numbers and billing privileges. Some Medicare-enrolled suppliers fail to maintain even the most basic Medicare standards – for example, maintaining a physical facility, or being open during reasonable business hours.

In 2006, we conducted unannounced site visits to 1,581 DME suppliers in south Florida after learning of allegations of noncompliance with Medicare standards in that geographic area.[2] We found that 31 percent of these DME suppliers did not maintain physical facilities or were not open and staffed during business hours. Another 14 percent of suppliers were open and staffed but did not meet additional requirements we reviewed. We recommended several steps that CMS could take to strength the provider enrollment process.

In 2007, OIG expanded its review of DMEPOS supplier enrollment by conducting unannounced site visits to 905 suppliers in Los Angeles County.[3] We found that 13 percent of suppliers did not maintain a physical facility or were not open when we visited and that an additional 9 percent did not meet additional standards we reviewed. We again recommended that CMS strengthen the supplier enrollment process and ensure that suppliers meet Medicare supplier standards. In response to our recommendations, CMS stated that, among other actions, it had increased the frequency of unannounced site visits; begun targeted background checks of suppliers in high-fraud areas; and implemented a mandatory accreditation process, in part, to prepare for the Competitive Bidding Program.

Payment: Medicare pays too much for certain DME items, resulting in waste for legitimate claims and making fraudulent billing more lucrative

It is imperative that Medicare payments for items and services be reasonable and consistent with market prices. When reimbursement methodologies do not respond effectively to changes in the marketplace, the program and its beneficiaries bear the cost in the form of increased Trust Fund expenditures, increased out-of-pocket costs for beneficiaries, and higher Part B premiums. Misalignment between payments and market prices and costs can also lead to excessive profits, which makes DME in particular a lucrative target for criminals, who can even reinvest some of their profits in kickbacks for additional referrals. If Medicare acted as a more prudent purchaser of DME, the Trust Fund and beneficiaries could save billions of dollars lost to waste, fraud, and abuse.

OIG reviews over the past two decades have determined that for certain items, the program pays too much. We have identified payment misalignments for a wide variety of DMEPOS items, ranging from power wheelchairs and oxygen equipment to wound care supplies and saline solution. For example, we found that in 2007, Medicare allowed, on average, about $4,000 for standard power wheelchairs that cost suppliers, on average, about $1,000 to acquire. Based on these findings, OIG recommended that CMS better align payment amounts with acquisition costs

[2] "South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits" (OEI-03-07-00150). March 2007.
[3] "Los Angeles County Suppliers' Compliance With Medicare Standards: Results From Unannounced Site Visits" (OEI-09-07-00550). February 2008.

by (1) using information from the Competitive Bidding Program, (2) seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes, or (3) using its inherent reasonableness authority.

This pricing disparity also makes wheelchairs an attractive target for fraud. We have found that fraudulent suppliers often supply unneeded and unwanted wheelchairs to beneficiaries because the payment from Medicare exceeds their purchase costs by such a large margin that it is lucrative to supply unnecessary wheelchairs.

In 2009, we found significantly misaligned prices for negative pressure wound therapy pumps, a type of DME used to treat serious wounds. In 2007, Medicare reimbursed suppliers for these pumps based on a purchase price of more than $17,000. We found that by comparison, suppliers paid, on average, approximately $3,600 for new pump models. The reason for this disparity lies in the history of this item and Medicare's inability to keep pace with market prices. When Medicare first started covering the pumps in 2001, it covered only one model, which was manufactured and supplied by only one company. In 2005, Medicare expanded its coverage to include several new pump models manufactured by other companies. While new pump models were significantly less expensive than the original model, Medicare continued to reimburse suppliers for these new pumps based on the original pump's purchase price. OIG recommended that to correct this pricing disparity, CMS use its inherent reasonableness authority to reduce the reimbursement amount for the pump and include the pump in the Competitive Bidding Program.

In addition, for over 20 years, OIG has identified and reported on misalignments in payments for home oxygen equipment. In 2006, we reported that Medicare allowed approximately $7,200 in rental payments over 36 months for an oxygen concentrator that cost approximately $600 to purchase. Beneficiary coinsurance alone for renting an oxygen concentrator for 36 months exceeded $1,400 – more than double the purchase price. The same study found that maintenance and servicing requirements for oxygen concentrators are minimal, making the difference between Medicare payments for rentals and acquisition cost more troubling. Since our report was issued, CMS has changed its payment methodology for home oxygen equipment to more accurately take into account maintenance and servicing costs, although we continue to recommend that the statutory rental period be shortened to from 36 to 13 months.

Compliance: Compliance programs and education can assist legitimate DME suppliers in billing appropriately

While much of OIG's work focuses on unscrupulous suppliers, they are the minority. Most DMEPOS suppliers are legitimate suppliers seeking to provide necessary items to beneficiaries. A key part of OIG's health care integrity strategy is to educate and assist these well-intentioned providers in fully complying with Medicare laws and regulations.

OIG is planning a Provider Compliance Training Initiative to bring together representatives from a variety of government agencies to deliver compliance training at no cost to local provider, legal, and compliance communities. The training sessions are scheduled to be held in 2011 in several locations across the country. We aim to educate communities about fraud risk areas uncovered by OIG's work and to share compliance best practices so that providers can

strengthen their own compliance efforts and more effectively identify and avoid illegal schemes that may be targeting their communities. This initiative will supplement OIG's extensive written guidance in these areas that is available on our Web site, including our compliance program guidance tailored specifically to the DME sector. We believe these efforts to educate provider communities, including DME suppliers, can help foster a culture of compliance and protect the Federal health care programs and beneficiaries.

OIG also incorporates compliance requirements into the resolution of certain civil and administrative cases that the Government has settled with DMEPOS suppliers. Frequently, the wrongdoing in these cases involves failure to support the medical necessity of the DMEPOS billed to Medicare. In such cases, OIG may enter into corporate integrity agreements with these suppliers. Under a corporate integrity agreement, the supplier must implement a compliance program, train employees, and hire an outside auditor to annually test a sample of its claims. This impetus to devote resources to compliance often leads to improved attention to and compliance with Medicare laws governing reimbursement and saves the Government money and resources in combating fraud. We are hopeful that the compliance programs mandated by the Affordable Care Act (ACA) will similarly improve compliance in the industry.

Oversight: Vigilant monitoring through data analysis and claims review is critical to preventing and detecting fraud, waste, and abuse

In addition, it is critical that the Government vigilantly monitor the Medicare program to swiftly detect and respond to fraud, waste, and abuse when it does occur. Recently, innovative uses of information technology and data analysis have dramatically enhanced the Government's ability to take a proactive approach to fighting fraud and abuse. Finally, a thorough review of claims and supporting documentation is sometimes necessary to determine whether DMEPOS claims were appropriately paid. Improper payments are a serious issue for DMEPOS in particular. In 2009, CMS reported an overall Medicare fee-for-service error rate of 7.8 percent; however, the payment error rate for Medicare DMEPOS claims was 51.9 percent.

In 2009, OIG organized the multidisciplinary, multiagency Advanced Data Intelligence and Analytics Team (Data Team) to support the work of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). The Data Team is composed of experienced OIG special agents, statisticians, programmers, auditors, analysts, and DOJ analysts. Their work combines sophisticated data analysis with criminal intelligence gathered from special agents in the field to more quickly identify health care fraud schemes, trends, and geographic "hot spots" to support the efficient and effective deployment of law enforcement resources.

Such advanced data analysis also enables OIG to alert CMS to patterns of potential fraud and abuse so that it can take appropriate prevention and oversight measures. For example, an OIG claims analysis revealed that in 2007, Medicare allowed more than $6 million for DME claims with invalid referring physician identifiers and $28 million for claims with inactive physician identifiers. Based on this analysis, we recommended that CMS update its claims-processing system to ensure that referring physician identifiers are valid and active. Had this capability been in place in 2007, Medicare could have avoided $34 million in improper payments.

Similarly, in an April 2009 study, OIG reported that south Florida accounted for 17 percent of Medicare's total spending for inhalation drugs in 2007, although only 2 percent of Medicare beneficiaries live in that area. Medicare Part B covers inhalation drugs when they are used in conjunction with DME. On 62 percent of these south Florida claims, the beneficiaries did not have Medicare-billed office visits or other services in the preceding 3 years with the physicians who reportedly prescribed the drugs. Using claims edits to detect these and other suspicious patterns in real time could greatly reduce vulnerability to fraud and abuse by preventing and allowing swift recovery of improper payments.

OIG has also conducted numerous in-depth reviews of DMEPOS claims and background documentation to determine whether items were provided and claims were paid appropriately. We have consistently found patterns of overutilization and failure to comply with Medicare requirements. For example, a recent review determined that 60 percent of Medicare claims for standard and complex rehabilitation power wheelchairs that beneficiaries received in the first half of 2007 did not meet documentation requirements. These claims accounted for $112 million in improper Medicare payments. Beneficiaries were responsible for paying $22 million of this amount. In another review, OIG examined whether suppliers that had expressly indicated (through a claims modifier) that they maintained required documentation on file in fact had that documentation. Most suppliers did not, resulting in estimated $126 million in improper payments.

Similarly, in 2009 we reviewed claims for pressure reducing support surfaces, which are used to treat and prevent bedsores. We found that for the first half of 2007, 86 percent of claims for certain categories of support surfaces did not meet Medicare coverage criteria. This amounted to an estimated $33 million in inappropriate payments during that time. Errors included undocumented or insufficiently documented claims, medically unnecessary claims, and other billing errors.

Response: OIG-DOJ Strike Forces have responded swiftly and effectively to DME fraud schemes; CMS efforts to remedy program vulnerabilities are also essential

OIG and DOJ are working in partnership to accelerate the Government's response to fraud schemes by reducing the time needed to detect, investigate, and prosecute fraud. We have deployed Strike Forces in geographic "hot spots" with high concentrations of Medicare fraud. Each Strike Force team includes agents from OIG and the Federal Bureau of Investigation and attorneys from DOJ and often State and local law enforcement. The team uses data analysis, combined with field intelligence from our special agents, to identify criminals committing health care fraud and to track fraud trends.

The Strike Force model has proven highly successful, particularly for combating DMEPOS fraud, and is a powerful antifraud tool. This collaborative, data-driven model has significantly reduced the time it takes from fraud detection to prosecution. Strike Forces also have a powerful deterrent effect. For example, according to Medicare data, in the first 12 months of establishing our Strike Force in Miami, Medicare billing for DMEPOS in Miami decreased by 63 percent, a drop of more than $1.7 billion, compared to billing in the year before.

Unfortunately, some of CMS's administrative efforts to shut down fraudulent DMEPOS suppliers have met challenges. For example, as a result of the OIG site visits in south Florida, CMS revoked the billing numbers of 491 suppliers. However, OIG found that nearly half of these suppliers appealed and received hearings; hearing officers reinstated the billing privileges for 91 percent of these suppliers. Two-thirds of suppliers whose billing privileges were reinstated have subsequently had their privileges revoked or inactivated. Further, the U.S. Attorney's Office has indicted 18 individuals connected to 15 of the 222 reinstated suppliers. To date, 16 of these 18 defendants have been convicted and were each ordered to pay between $25,000 and $11 million in restitution. These 16 defendants were also sentenced to jail terms ranging from 1 to 4 years. Improvements are needed to ensure that once identified, fraudulent suppliers are not allowed to reenter the program and continue to defraud Medicare.

CMS has taken several positive steps to respond to DMEPOS fraud vulnerabilities by implementing program safeguards. For example, CMS's most significant recent action was to require that all DMEPOS suppliers obtain accreditation and purchase surety bonds that protect Medicare in the event that a supplier is unable to make restitution for improper payments. Both of these requirements were implemented in preparation for the Competitive Bidding Program, although they apply to DMEPOS suppliers more broadly. CMS also reports that it is enhancing its field operations to more closely monitor areas of high vulnerability, including DMEPOS fraud. Lastly, a final rule published at the end of August strengthens enrollment standards in a variety of ways, including requiring that DMEPOS suppliers be open at least 30 hours per week and requiring that they maintain an appropriate physical facility that is accessible to the public.

The Affordable Care Act establishes new authorities and requirements to strengthen enrollment scrutiny, oversight, and response to address fraud vulnerabilities

The ACA provides the Secretary with new authorities and imposes new requirements consistent with OIG's health care integrity strategy and recommendations. These include promoting data access and integrity; requiring actions to strengthen provider enrollment standards; promoting compliance with program requirements; and enhancing program oversight, including requiring greater reporting and transparency. Among the most significant statutory changes are provisions requiring that only Medicare-enrolled providers may order or prescribe DMEPOS for Medicare beneficiaries; authorizing enhanced, risk-based screening for Medicare providers and suppliers; and permitting CMS to impose temporary enrollment moratoriums on providers and suppliers if necessary to prevent and combat fraud.

Specifically, the ACA requires the Secretary to establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Secretary is to determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier. At a minimum, providers and suppliers will be subject to licensure checks. The ACA also authorizes the Secretary to impose additional screening measures based on risk, including fingerprinting, criminal background checks, multi-State database inquiries, and random or unannounced site visits.

Ensuring the integrity of information is also crucial, and the ACA provides new accountability measures toward this end. The ACA authorizes OIG to exclude from the Federal health care

programs entities that provide false information on any application to enroll or participate in a Federal health care program. The ACA also provides new civil monetary penalties for making false statements on enrollment applications; knowingly failing to repay an overpayment; and failing to grant timely access to OIG for investigations, audits, or evaluations.

Changes to align payments for DMEPOS are still needed to address waste, fraud, and abuse

Although these new ACA requirements and CMS program integrity efforts represent important steps forward in combating fraud in the DMEPOS program, they do not fully address all vulnerabilities associated with this important benefit. Most notably, they do not fix misalignments between Medicare payments and market prices. The program will continue to be vulnerable to excessive costs and bad actors will continue to be attracted by the prospect of excessive profits so long as the payment misalignments highlighted in OIG's work persist.

OIG's body of work has consistently highlighted the need for Medicare to change payment methodologies in order to pay appropriately for DMEPOS. The ongoing price disparities that OIG has found exist largely because payments are based on charge data submitted to the program in 1986. Although CMS has the authority to make certain adjustments to the DMEPOS fee schedule, congressional action would be needed to reform the DMEPOS fee schedule to align initial payment rates more closely with market prices and enable CMS to adjust payments in response to changes in market prices. Competitive bidding is one mechanism to better align payments with market prices; however, the Competitive Bidding Program has not been implemented yet and not all DMEPOS items will be subject to competitive bidding.

The Competitive Bidding Program is one potential solution to address payment misalignments and further facilitate program integrity oversight

The Competitive Bidding Program has the potential to address vulnerabilities identified by OIG's work. Primarily, it holds the promise to address payment vulnerabilities for the items subject to competitive bidding by better aligning reimbursement for these items with market prices. It also includes important enrollment safeguards, such as licensure requirements, and provides a mechanism for ensuring that CMS has better information about the suppliers when granting billing privileges. Finally, it may facilitate oversight efforts by limiting the pool of providers to only those who have been approved through the competitive bidding process and pass rigorous enrollment standards.

It is critical that these and other program vulnerabilities be addressed, be it through competitive bidding or otherwise. Whatever processes are implemented, the end result must be Medicare payments that appropriately compensate providers, ensure adequate access for beneficiaries, are responsive to market changes, and allow Medicare to use its size to be a prudent purchaser of services. If the Competitive Bidding Program is not implemented as currently planned, other solutions to these problems must be found. Otherwise, the Medicare program and its beneficiaries will continue to lose scarce health care dollars to fraud, waste, and abuse.

Conclusion

I appreciate the opportunity to appear before you today to discuss OIG's substantial body of work on fraud, waste, and abuse associated with Medicare's DMEPOS benefit. OIG has a long history of analyzing these issues from investigative, audit, evaluation, and compliance standpoints. We have consistently made recommendations to correct the vulnerabilities we have identified and, often, CMS or Congress has implemented changes. Despite this, we continue to find significant problems, often to an alarming extent. We remain committed to any effort that will address the issues we have identified. The Medicare Competitive Bidding Program holds promise to address problems associated with supplier enrollment and payment misalignments. If policymakers consider a different course, it remains imperative to take prompt, appropriate corrective action to ensure that the DMEPOS benefit is protected from fraud, waste, and abuse. If competitive bidding or other action is implemented, my office remains committed to effective monitoring to ensure that beneficiaries continue to have access to reasonably priced, medically necessary, quality services.

Thank you for your commitment to ensuring the integrity of the Medicare program. I would be happy to answer any questions.

Mr. PALLONE. Thank you, Mr. Levinson.
Ms. King.

STATEMENT OF KATHLEEN KING

Ms. KING. Mr. Chairman and members of the subcommittee, I am pleased to be here today to discuss Medicare's competitive bidding program for DME.

Medicare's DME program for competitive bidding was implemented in part to save Medicare money. Both we and the Office of the HHS Inspector General have reported that Medicare and its beneficiaries have paid higher than market prices for various medical equipment and supplies. These overpayments increase cost to both Medicare and its beneficiaries.

Today I am going to focus on three problem areas we identified in our November 2009 report and how CMS is addressing those problems. These three areas are: providing suppliers with bid submission information, the electronic bidding submission system and the bid disqualification notification process.

First, in the bidding process for round one, we found several problems regarding the timeliness of information provided by CMS and lack of clarity in bid submission information provided to bidders. We also found that CMS was not able to inform suppliers what required financial documentation was missing or incomplete. In contract, for the round one re-bid, CMS provided information earlier to suppliers, took several steps to make its financial documentation instructions clear and notified suppliers when their financial documentation was incomplete.

In response to concerns expressed during round one that winning suppliers did not have the necessary capacity to fulfill their contracts, for the re-bid CMS developed a systematic method for reviewing suppliers' capacity and expansion plans. To address concerns that some suppliers were awarded contracts in round one in States for which they were not licensed, CMS clarified the requirement that suppliers be licensed in all States for which they submitted bids and provided directories to assist suppliers in identifying state licensing requirements.

Secondly, with regard to the electronic bid submissions, we found that the bid submission system had several operational problems that affected suppliers' ability to submit their bids. For the re-bid, CMS developed a new electronic bid submission system, DBidS, which was designed to be user friendly, easier for suppliers to navigate and capable of providing detailed bidding instructions in user-friendly language. DBidS also has status indicators to show whether the bidding forms are complete and links to direct bidders to incomplete data.

For the third issue, the bid disqualification process, in the first round almost half of the bids were disqualified. CMS conducted a post-bidding review process through which the agency reversed some of these decisions. However, CMS did not effectively notify suppliers about the opportunity for this post-bidding review process. To improve future rounds, we recommended that if CMS decides to conduct a review of disqualification decisions made during round one, they should notify all suppliers of that process, give

suppliers and equal opportunity for review and clearly indicate how they can request a review. CMS agreed with our recommendations.

Beginning in July 2010, CMS sent notification letters to winning suppliers offering them contracts but did not notify the losing suppliers. CMS informed us after the round one re-bid contracting process is complete, they will send letters to disqualified suppliers explaining why they were disqualified. CMS said the letters will also explain the process through which suppliers may ask questions and express concerns, and they said if they find that in the course of responding to these concerns they determine that an error has been made, it is possible that a contract would be offered to a supplier.

We plan to do further work regarding the round one re-bid. As required by MIPPA, we will examine the program's impact on Medicare beneficiary access to items and services and on small suppliers, among other topics. Our study is to be completed a year after payments on the first round are made.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions. Thank you.

[The prepared statement of Ms. King follows:]

United States Government Accountability Office

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Testimony
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MEDICARE

CMS Has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid

Statement of Kathleen M. King
Director, Health Care

GAO-10-1057T

GAO
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Highlights

Highlights of GAO-10-1057T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

To reduce spending on durable medical equipment (DME) and related items, under federal law the Centers for Medicare & Medicaid Services (CMS) is phasing in, with several rounds of bidding, a competitive bidding program (CBP) for certain DME and other items. Because of numerous concerns, the Medicare Improvements for Patient and Providers Act of 2008 (MIPPA) terminated the CBP round 1 supplier contracts and required CMS to repeat the CBP round 1, the rebid that began in 2009.

In November 2009, GAO issued the report *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program* (GAO-10-27) that documented problems in CMS's implementation of CBP round 1. This statement discusses some of the problems GAO identified and how CMS has or plans to address them in the ongoing CBP rebid bidding process, particularly (1) the bid submission information provided to suppliers, (2) the electronic bid submission system, and (3) the bid disqualification notification process.

For the 2009 report, GAO reviewed data provided by CMS and relevant laws and regulations, and interviewed CMS officials. For this statement, GAO also obtained select information on how CMS addressed the CBP round 1 problems identified in GAO's report by reviewing agency documents and interviewing CMS officials in August and September 2010.

View GAO-10-1057T or key components. For more information, contact Kathleen M. King (202) 512-7114 or kingk@gao.gov.

September 15, 2010

MEDICARE

CMS Has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid

What GAO Found

In the November 2009 report on CBP round 1, GAO noted that problems with the bidding process included poor timing and lack of clarity in bid submission information and the inability to inform suppliers of missing financial documentation. Several times after the CBP round 1 bid window opened, CMS provided new bidding information and clarified other bidding information. The bid window was also extended beyond the initial deadline. These changes made it more difficult for suppliers to submit correct bids. CMS improved implementation of these steps in the bidding process for the CBP round 1 rebid. For example, for the CBP round 1 rebid, CMS provided bidding information to suppliers prior to the bid window opening, including the rebid's request-for-bid instructions, which were available to potential bidding suppliers for over 2 months before the bid window opening. CMS also provided clearer financial documentation instructions and additional financial documentation tools to guide suppliers in the CBP round 1 rebid. For example, the request-for-bid instructions included a chart that more clearly explained which documents were to be submitted by the supplier's business type, for example, a sole proprietorship. CMS also conducted a financial document review during the round 1 rebid, which informed suppliers whether their bid submission was missing required financial documents. Of the 321 suppliers that were notified they had missing documentation, only 14 did not subsequently submit the missing documents.

As CMS acknowledged, suppliers had difficulty entering bidding information in the bid submission system used in CBP round 1 and its user guide was not sufficiently detailed. CMS developed a new electronic bid submission system for the CBP round 1 rebid. CMS officials told us that the new system did not have significant operational issues and only a few suppliers experienced minor problems.

GAO found that CMS had not effectively notified all suppliers about the opportunity for a postbidding review process in CBP round 1. To address GAO's 2009 recommendation that the agency effectively notify all suppliers of all aspects of the CBP round 1 rebid and future rounds, including any process to review disqualifications, CMS officials stated that the agency plans to notify the losing suppliers of the disqualification reasons by sending each of these suppliers a letter that will explain the process for asking questions or expressing concerns. Officials also stated that in the course of responding to suppliers' questions or concerns, if CMS determines an error was made, it is possible that the supplier may be offered a contract.

In commenting on the information presented in this testimony, CMS officials stated they appreciated GAO noting the administrative improvements to the competitive bidding process the agency made for the round 1 rebid. The officials further stated that they believe that CMS made many improvements to the CBP.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Medicare[1] competitive bidding program for selected durable medical equipment (DME) and certain other items.[2] My testimony today is focused on how the Centers for Medicare & Medicaid Services (CMS)[3] is addressing bidding process problems we identified during round 1 of the competitive bidding program—conducted from 2007 to 2008—in our November 2009 report,[4] and steps CMS has taken to address those problems for the program's round 1 rebid bidding process, which is currently under way. Competitively determined Medicare payments for items and services covered under the round 1 rebid will be effective on or after January 1, 2011.

In 2009, Medicare spent $8.1 billion on DME, other items, and related supplies.[5] Since 1989, Medicare has paid for most DME through fee schedules. Medicare payment for DME is generally equal to 80 percent of the lesser of either the supplier's actual charge or the Medicare fee schedule for a particular item or service.[6] Both we and the Department of Health and Human Services' (HHS) Office of Inspector General have reported that Medicare and its beneficiaries have sometimes paid higher-

[1]Medicare is the federal health insurance program that currently serves about 46.3 million elderly and disabled individuals.

[2]DME is equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. Items covered by the competitive bidding program include selected DME and related supplies and enteral nutrients and related equipment and supplies.

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

[4]See GAO, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, GAO-10-27 (Washington, D.C.: Nov. 6, 2009). Other related GAO products are listed at the end of this statement.

[5]Other items include prosthetic devices (other than dental), which are defined as devices needed to replace body parts or functions, such as artificial limbs, enteral nutrition, and cardiac pacemakers, and orthotic devices, which are defined as providing rigid or semirigid support to weak or deformed body parts or restricting or eliminating motion in a diseased or injured part of the body, such as leg, arm, back, and neck braces. Medicare-reimbursed supplies are items that are used and consumed with DME, such as drugs used for inhalation therapy, or that need to be replaced frequently (usually daily), such as surgical dressings.

[6]Medicare adjusts fee schedules for DME for each state, reflecting geographic price differences which are subject to national floor and ceiling limits.

than-market rates for various medical equipment and supply items.[7] These overpayments increase costs to both Medicare and its beneficiaries.[8] As we have previously stated, competitive bidding can reduce Medicare program payments by providing an incentive for suppliers to accept lower payment amounts for items and services to retain their ability to serve Medicare beneficiaries and potentially increase their market share.[9]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[10] required CMS to phase in a competitive bidding program (CBP) for DME suppliers. CMS contracted with Palmetto GBA to implement the CBP bidding and contract award process and with Maricom to develop a Web-based electronic bid submission system. CBP round 1 was conducted in 2007 and 2008 for 10 competitive bidding areas.[11] For the bidding, CMS chose certain DME items in 10 product categories—generally high cost and high volume items and services—that were most likely to result in

[7]GAO, *Medicare: Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical*, GAO-08-767T, (Washington, D.C.: May 6, 2008); GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, GAO-04-765, (Washington, D.C.: Sept. 7, 2004); Department of Health and Human Services Office of Inspector General, *A Comparison of Prices for Power Wheelchairs in the Medicare Program*, OEI-03-03-00460 (Washington, D.C.: April 2004); and Janet Rehnquist, Inspector General, Department of Health and Human Services, *Medicare Reimbursement for Medical Equipment and Supplies*, testimony before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, 107th Cong., 2nd sess., June 12, 2002.

[8]In general, Medicare beneficiaries pay 20 percent of the Medicare reimbursement rate for DME after reaching their annual deductible.

[9]GAO-08-767T.

[10]Pub. L. No. 108-173 § 302(b), 117 Stat. 2066, 2224 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3). In this statement, we refer to the competitive acquisition program as the competitive bidding program.

[11]To begin the program's national phase-in, the CBP round 1's 10 competitive bidding areas were chosen from the largest metropolitan statistical areas (MSA). The 10 CBAs had to be selected from the largest MSAs. The 10 CBAs were Charlotte (Charlotte-Gastonia-Concord, North Carolina and South Carolina); Cincinnati (Cincinnati-Middletown, Ohio, Kentucky, and Indiana); Cleveland (Cleveland-Elyria-Mentor, Ohio); Dallas (Dallas–Fort Worth–Arlington, Texas); Kansas City (Kansas City, Missouri and Kansas); Miami (Miami–Fort Lauderdale–Miami Beach, Florida); Orlando (Orlando-Kissimmee, Florida); Pittsburgh (Pittsburgh, Pennsylvania); Riverside (Riverside–San Bernardino–Ontario, California); and San Juan (San Juan–Caguas–Guaynabo, Puerto Rico).

Medicare savings if competitively acquired.[12] The round 1 suppliers submitted bids for supplying one or more of these 10 DME product categories in 1 or more of the 10 competitive bidding areas. There were 6,374 bids submitted by 1,010 suppliers. In March 2008, CMS began offering contracts to winning suppliers to provide DME to Medicare beneficiaries. The contracts between CMS and suppliers became effective on July 1, 2008.

Round 1's bid submission and contract award processes raised concerns about the CBP implementation. Therefore, on July 15, 2008, implementation of the CBP round 1 was stopped—after 2 weeks—by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which terminated the contracts already awarded to suppliers, delayed the program's restart, and required CMS to repeat the competition for CBP round 1 in 2009[13]—referred to in this statement as the CBP round 1 rebid.[14] MIPPA also imposed additional criteria for how CMS should conduct later CBP rounds, including the round 1 rebid and subsequent rounds that will expand the CBP to additional areas.[15]

[12]CBP round 1's 10 product categories were oxygen supplies and equipment; standard power wheelchairs, scooters, and related accessories; complex rehabilitative power wheelchairs and related accessories; mail-order diabetic supplies; enteral nutrients, equipment, and supplies; 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; walkers and related accessories; and support surfaces (limited to group 2 mattresses and overlays—pressure reducing support surfaces for persons with or at high risk for pressure ulcers—in the Miami and San Juan CBAs only).

[13]Pub. L. No. 110-275, § 154, 122 Stat, 2494, 2560 (2008) (codified, as amended, at 42 U.S.C. § 1395w-3).

[14]To ensure budget neutrality, that is, to compensate for the loss of the projected savings from the CBP's round 1 delay, beginning January 1, 2009, MIPPA reduced the national Medicare reimbursement payments by 9.5 percent nationally for items and services that had been included in CBP round 1.

[15]CMS issued an interim final rule implementing these MIPPA provisions. Centers for Medicare & Medicaid Services, *Medicare Program: Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) by Certain Provisions of MIPPA*, 74 Fed. Reg. 2873 (Jan. 16, 2009). In this rule, CMS clarified that with the exception of the new provisions in this rule, the CBP final rule published on April 10, 2007, *Medicare Program: Competitive Acquisition for Certain DMEPOS and Other Issues*, 72 Fed. Reg. 17, 992, would continue to govern implementation of the CBP for DME and other items.

Our November 2009 report documented round 1 implementation problems. We found, for example, that CMS did not provide suppliers with timely and clear bid submission information, used an inadequate electronic bid submission system, and did not have a process to inform bidders of missing financial documentation—42 percent of all submitted bids were disqualified due to incomplete financial documentation. In our report, we recommended that if CMS decides to review suppliers' disqualified bids during the round 1 rebid and future rounds, it should notify all suppliers of any such process, give suppliers equal opportunity for such reviews, and clearly indicate how suppliers can request a review.

In October 2009, CMS began the CBP round 1 rebid process.[16] The bid window closed in December 2009. There were 6,215 complete bids submitted by 1,011 bidding suppliers. On July 1, 2010, CMS announced the competitively determined DME single payment amounts, which are the new payment amounts that Medicare will pay for each item covered under the CBP. These payments will replace the applicable fee schedule amounts for the selected DME items in the competitive bidding areas. Under the round 1 rebid, CMS estimated that compared to the 2009 Medicare fee schedule, the volume-weighted reduction in CBP's single payment amounts for items averaged 32 percent. Under round 1, the estimated payment reductions compared to the 2008 Medicare fee schedule averaged 26 percent.[17] CMS also announced on July 1, 2010, that it would begin mailing contract offers to winning suppliers.[18] CMS officials informed us that 1,287 bids are included in the initial wave of contract offers. CMS

[16]In the CBP round 1 rebid, the product categories were revised to delete the negative pressure wound therapy category and to exclude group 3 complex rehabilitative power wheelchairs from the entire CBP, and to delete San Juan (San Juan–Caguas–Guaynabo, Puerto Rico) as a competitive bidding area.

[17]According to CMS officials, the savings estimate for each combination of competitive bidding area and product category was derived by multiplying the difference between the 2009 Medicare fee schedule for each item in the product category and the CBP-derived single payment amounts by the item's percentage share of the total number of units represented by all items in the product category provided by Medicare in 2008. In both CBP round 1 and the CBP round 1 rebid, the items in the mail-order diabetic supplies product category had the largest reductions, with the difference between the single payment amounts and the Medicare fee schedule averaging 43 and 56 percent, respectively.

[18]CMS officials informed us that if any winning supplier offered a CBP round 1 rebid contract decides not to accept the contract, it is possible that a losing supplier may later be offered the contract. The Palmetto GBA CBP Web site—www.dmecompetitivebid.com—provided suppliers a fact sheet on contract supplier obligations. Contract suppliers are winning suppliers that enter into a contract with CMS to provide specific items in the area for which the suppliers submitted a competitive bid.

officials also stated that they plan to announce the winning suppliers that accepted contracts in September 2010.[19]

In my testimony today, I will discuss problems we identified in the round 1 competitive bidding process and how CMS has or plans to address the problems in the ongoing rebid bidding process regarding (1) providing suppliers with bid submission information, (2) use of an electronic bid submission system, and (3) the bid disqualification notification process.

For our 2009 report, we reviewed data provided by CMS and Palmetto GBA; reviewed federal laws, regulations, and policies concerning the bidding and contract award processes; reviewed documents from the CBP round 1 bidding process, and interviewed CMS and Palmetto GBA officials about the CBP round 1 bid process and efforts to resolve problems that arose. For this testimony, we also obtained information on CMS responses to problems we identified in our 2009 report by reviewing agency documents and interviewing CMS officials. We also reviewed the available materials provided on the CMS and Palmetto GBA CBP Web sites and analyzed the results from the inquiries from suppliers received by the Palmetto GBA customer service center. We shared the information in this statement with CMS officials. Our work was performed in accordance with generally accepted government auditing standards for the 2009 report from June 2008 through September 2009 and for this testimony from August through September 2010. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[19]CMS plans to begin the CBP round 2 competitive bidding process in 2011. The Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 6410, 124 Stat. 119, 773 (2010) increases the number of round 2 competitive bidding areas from 70 to 91 of the largest MSAs, accelerating the CBP's implementation and its projected savings.

Problems Were Identified in the CBP Round 1 Bidding Process in Providing Suppliers with Bid Submission Information, but Some Improvements Were Made in the CBP Round 1 Rebid Process

For CBP round 1, we found problems with the bidding process, including poor timing and lack of clarity in bid submission information and CMS's inability to inform suppliers of missing financial documentation. In comparison with CBP round 1, CMS provided CBP round 1 rebid bidding information to suppliers earlier, and its financial documentation instructions were clearer and suppliers were notified of missing documentation. CMS also added program information about determining suppliers' capacity, and provided directories to inform suppliers about state licensure requirements.

CMS Had Difficulty Providing Clear Bidding Information to Suppliers in CBP Round 1, but Improved Its Communication about Bidding Information for the CBP Round 1 Rebid

CMS had difficulty providing clear bidding information in CBP round 1. For example, CMS provided new bidding information several times after the bid window opened, such as announcing the 10 financial measures used to evaluate the financial viability of bidding suppliers; clarified CBP round 1's bidding information in response to supplier confusion, such as providing additional explanatory information concerning the request-for-bid instructions; and extended the bid window deadline. These changes in bidding information made it more difficult for suppliers to submit correct bids.[20] CMS and Palmetto GBA acknowledged that during CBP round 1 suppliers did not always understand the request-for-bid instructions. The instructions were not available to suppliers until the day the bid window opened. During the first 2 months of the bid window, while suppliers were preparing their bid submissions, Palmetto GBA held informational bidder conference calls on how to submit bids and maintained audio recordings on the CBP Web site for a limited time. Questions also were not organized by subject matter, and while the Web site had a frequently asked questions section, it was difficult for suppliers to determine when questions had been added.

[20]The CBP round 1 bid window was extended three times resulting in a 4-month-long window. Although suppliers could revise their bid submissions throughout the bid window, when additional information was provided those that believed they had submitted completed bids had to review them to ensure that they were still correct.

CMS improved its communication with suppliers about bidding information for the CBP round 1 rebid. For example, CMS provided suppliers with bidding information before the bidding window opened on October 21, 2009, so that bid window extensions were not needed.[21] Prior to the bid window opening, the rebid's request-for-bid instructions had been available to potential bidding suppliers for over 2 months, since August 3, 2009, and CMS had already held seven informational bidder conference calls.[22] Transcripts, audio recordings, and PowerPoint presentations from the calls were available on the Palmetto GBA CBP Web site throughout the round 1 rebid. CMS made two minor clarifications to the CBP round 1 rebid instructions.[23] First, on the day the bid window opened, CMS provided the actual bid submission deadlines, including the covered document review date,[24] and provided further instructions on how a supplier needed to approve a bid in the online bidding system and would submit the required hard copy financial documents. Second, on November 17, 2009, CMS clarified that the financial statements for the last operating year that suppliers were required to submit as part of their bids could be for either calendar or fiscal years.

For the CBP round 1 rebid, Palmetto GBA maintained suppliers' frequently asked questions on the CBP's Web site by topic. The questions were provided for three topics—Bidding Guidelines, Bidding Process, and Payment Policies—and dated in chronological order, unlike in CBP round 1, so suppliers could more easily determine when new ones were

[21]The CBP round 1 rebid's bid window was open for 60 days—October 21 through December 21, 2009. Under federal law and implementing regulations, subject to few exceptions, suppliers furnishing DME and other items on or after October 1, 2009, must have submitted evidence of accreditation to CMS and beginning October 2, 2009, suppliers must submit a surety bond when enrolling in Medicare, making a change in ownership, or responding to a re-enrollment request. For the round 1 rebid, CMS required suppliers to submit evidence of accreditation and surety bonds prior to submitting their bids. During CBP round 1, suppliers could submit bids even if their accreditation was still pending.

[22]CMS held an eighth special open door forum after the bid window opened to respond to suppliers' questions about the competitive bidding process.

[23]Before the bid window opened, CMS changed the instructions on August 24, 2009 to provide a link to the Financial Documents Chart in the Required Hardcopy Documents section of the CBP Web site, http://www.dmecompetitivebid.com/.

[24]MIPPA and implementing regulations defined the covered document review date as the later of (1) 30 days before the final date for the close of the bid window or (2) 30 days after the bid window opens. During the CBP round 1 rebid, CMS was required to notify eligible suppliers of missing financial documentation within 45 days of the covered review date. The CBP round 1 rebid's review date was November 21, 2009.

posted on the Web site. The Web site also has a "What's New" section to allow suppliers to find any new CBP information, for example, information for the suppliers that were offered contracts, such as the form to request that business locations be added or removed from their contracts.[25]

Unclear CBP Round 1 Financial Documentation Instructions Led to Many Bid Disqualifications, but CBP Round 1 Rebid Instructions Were Clearer

In our 2009 report, we found that financial documentation instructions were sometimes unclear in CBP round 1. CMS acknowledged that during CBP round 1 many suppliers had particular difficulty complying with the financial documentation[26] requirements and that the statement of cash flow—described as a statement of changes in financial position—was the document most often missing. We found that CMS's CBP round 1 financial documentation instructions did not clearly address differences among supplier business types—for example, a sole proprietorship business versus a publicly traded national corporation—and among the financial documents needed to submit a bid for each type. Because business types could not easily be cross-referenced to the request-for-bid instructions, suppliers were at risk of submitting incomplete or inaccurate financial documentation. We also found that CMS's CBP round 1 request-for-bid instructions had inconsistent information about the requirements for the credit report and credit score submission. For example, the bid submission form stated that a credit rating and score—rather than using the term credit report—had to be submitted. Near the end of the bid window, Palmetto GBA then issued a "required document reminder" that all bidders had to submit both a credit report and a credit score.

For the CBP round 1 rebid, CMS clarified financial documentation instructions by providing additional tools to guide suppliers through the bid submission process.[27] The request-for-bid instructions included a chart—Required Financial Documents by Business Type—that more clearly explained which documents were to be submitted by business type. For example, the chart specified which portions of a supplier's tax return were required based on its business type such as a sole proprietorship.

[25]In addition, Palmetto GBA again had a customer service center to field inquiries from suppliers and individuals before, during, and after the bid window closed—7,637 phone and written inquiries had been made as of June 30, 2010.

[26]Financial documentation means a financial, tax, or other document required to be submitted in order to meet CMS's financial standards for the CBP.

[27]For the CBP round 1 rebid, suppliers were required only to submit 1 year of financial documentation instead of 3 years as was required in round 1.

The chart also included a credit report column that stated bidders must submit a "Credit Report with numerical score completed within 90 days of bid submission," and the bid instructions included the same description. To further assist suppliers to provide the correct financial documents, the instructions included a Required Financial Documents appendix with sample documents and more specific explanations of the income statement, balance sheet, statement of cash flow, revenue and expense portion of the tax return, and the credit report, along with a Checklist of Required Hardcopy Documents for Bid Submission.

For the CBP round 1 rebid, CMS officials told us they notified bidding suppliers that submitted their hard copy financial documents by the round's covered review date of any missing documents, as required by MIPPA.[28] Once notified, suppliers had 10 business days to submit their missing documentation.[29] CMS officials told us that 791 suppliers submitted their financial documentation by the CBP round 1 rebid covered document review date and 321 were notified that they had missing documentation. Fourteen suppliers did not subsequently submit the missing documents and their bids were disqualified. For this review, tax record documents were the most often missing financial documentation.

[28]The CBP round 1 rebid's covered review date was November 21, 2009. During the CBP round 1 rebid, CMS was required to notify eligible suppliers of missing financial documentation within 45 days after the end of the covered document review date. For future rounds, CMS must notify eligible suppliers of missing financial documentation within 90 days after the end of the covered document review date.

[29]This process only applies to the timely submission of financial documentation and does not apply to any determination by CMS as to the accuracy or completeness of the documentation submitted or whether the documents meet applicable financial requirements.

In CBP Round 1, Questions Were Raised about CMS's Ability to Estimate the Capacity of Suppliers to Furnish DME Items, but CMS Added a Systematic Method to Estimate Supplier Capacity for the CBP Round 1 Rebid

In CBP round 1, questions were raised about the capacity of some suppliers to fulfill their awarded contracts on day one of the CBP's contract period, including whether they had experience providing the DME product category, had business locations in the competitive bidding areas, and could expand their businesses, if needed, to supply all Medicare beneficiaries in their competitive bidding areas. CMS officials told us that the CBP's Program Advisory and Oversight Committee (PAOC)[30] raised concerns that suppliers new to a competitive bidding area, new to a DME product category, or that reported high capacity figures would not be able to increase reported capacity in time to meet the projected demand for the DME items in the competitive bidding areas.

To address the concerns, CMS officials told us that the agency added a systematic method of reviewing suppliers' capacity and expansion plans for the CBP round 1 rebid.[31] CMS developed a three-step method to determine whether a supplier new to a product category or a competitive bidding area or an experienced supplier that reported high capacity figures would be able to increase capacity to meet the projected demand for the DME items.[32] The three steps were as follows:

- First, CMS determined whether the total capacity of all experienced suppliers in the competitive bidding area reporting modest growth projections and eligible for a competitive bidding program contract offer could meet the projected demand for items in the contract's first year. If the capacity from these experienced suppliers was sufficient to cover the item demand on day one of the program, then the capacity offered by any

[30]The PAOC members were appointed by the HHS Secretary to advise CMS on implementing the CBP.

[31]CMS and Palmetto GBA provided a fact sheet explaining how a supplier should estimate its capacity to provide each item being bid to ensure that suppliers winning contracts could sustain this level of capacity throughout the entire competitive bidding area for the contract period. The sheet also explained that suppliers new to a product category, or new to a competitive bidding area, or that otherwise plan to increase their capacity beyond their current levels must submit expansion plans as part of their bid submissions.

[32]CMS officials told us that the ability of grandfathered suppliers or suppliers that are exempt from the CBP to cover a certain percentage of the beneficiary demand was not considered in reviewing contract suppliers' ability to meet demand on day one of the program. The CBP round 1 rebid fact sheets stated that grandfathered suppliers are suppliers that are not awarded a competitive bidding contract for furnishing oxygen and oxygen equipment or rented DME in a competitive bidding area and that decide to be grandfathered suppliers for the Medicare beneficiaries to whom they are furnishing these DME items at the time the CBP takes effect.

additional suppliers with expansion plans and eligible for a contract offer was considered surplus capacity and no further review was conducted.

- Second, if the total capacity of the experienced suppliers identified in step one did not meet the projected demand for the first year of the contract, then CMS reviewed the expansion plans provided by the new and high-growth or high-volume suppliers to verify their capacity to furnish the items. The expansion plan review involved an in-depth examination of the supplier's financial information, specifically to verify whether the supplier had the liquid assets and available credit needed to expand capacity. If the verified capacity from these suppliers with expansion plans was sufficient to meet demand, CMS determined that the suppliers eligible for a CBP contract offer had the ability to meet demand on day one of the program.

- Third, if the results of the first two steps indicated that more suppliers were needed to meet demand on day one of the program, CMS made more suppliers eligible for a CBP contract offer.

As of September 10, 2010, CMS had not disclosed how many capacity evaluations were conducted during the CBP round 1 rebid.

In CBP Round 1, CMS Awarded Some Contracts to Suppliers That Were Not Yet Licensed, but CMS Provided Directories to Inform Suppliers of State Licensure Requirements in the CBP Round 1 Rebid

In 2009, we found that some suppliers that won CBP round 1 contracts were not yet licensed in states where they would be operating. For the CBP round 1 rebid, CMS further clarified the state licensure requirement, stating that suppliers must be licensed for the product category in the competitive bidding area in which they are bidding, and if a competitive bidding area covers more than one state, the supplier needs to obtain applicable licensure in all states. In order to better inform suppliers about these licensure requirements, CMS and Palmetto GBA provided licensure state directories for the 11 states included in the CBP round 1 rebid competitive bidding areas. The directories, which served only as guides for suppliers, provided a list of licenses required by each state for each product category for suppliers with a physical location in that state.[33] Suppliers without a physical location in the state but that would be providing DME items and services to Medicare beneficiaries in the state were directed to consult the appropriate state licensing agency; contact information for those agencies was also provided. The suppliers were required to file copies of applicable state licenses with the National

[33]The directories list, for example, licensure for a home medical device retail license and a respiratory care practitioner license.

Supplier Clearinghouse—which processes Medicare enrollment applications by DME suppliers—prior to submitting a bid.

Electronic Bid Submission System Used in CBP Round 1 Had Operational Problems, and CMS Developed a New Bid System for the CBP Round 1 Rebid

CMS acknowledged that CBP round 1's competitive bid submission system—CBSS—had operational problems that affected suppliers' ability to submit their bids. These problems included, for example, loss of bid submission data caused by CBSS security features that automatically logged suppliers out after 2 hours and that timed out suppliers if there was no activity for 30 minutes, and cases when CBSS was unavailable because of unscheduled downtimes. Additionally, CBSS did not have a "cut and paste" function and manual data reentry was time-consuming and increased the risk of suppliers inputting incorrect data that could disqualify a bid. CMS officials also acknowledged that the CBSS user guide was not very detailed or user friendly.

CMS developed a new electronic bid submission—DBidS—for the CBP round 1 rebid. DBidS was designed to address CBSS's specific deficiencies by being more user friendly and easier for suppliers to navigate and providing a logical flow of the requested data, as well as detailed bidding instructions in user-friendly language. Suppliers were provided a DBidS reference guide on the DMEPOS Competitive Bidding Program Web site that included screen shot explanations for the bid submission Forms A and B.[34] It also has a "copy and paste" function for the transfer of certain data and many data-saving points to minimize loss of data. Suppliers could have more than one employee access DBidS at the same time, but to control data input DBidS will not allow more than one employee to input the same data at the same time. DBidS has status indicators to indicate whether the bidding forms are "complete," "incomplete," or "pending approval," and has links in the system to direct suppliers to the incomplete data. CMS officials told us that DBids did not have significant operational issues and only a few suppliers experienced minor problems.

[34]Suppliers submit two forms as part of their bid submission—Form A, which is the bid application, and Form B, which is the bidding form.

CMS Did Not Effectively Notify All Suppliers about the Postbidding Review Opportunity in CBP Round 1, and Plans to Communicate with All Losing Suppliers in the CBP Round 1 Rebid after Contract Suppliers are Announced

In CBP round 1, CMS sent notification letters to both the winning and losing suppliers before announcing the final winning suppliers that accepted contracts for the CBP. The letters sent to suppliers that had bids disqualified included an attachment using seven general reason codes to explain the grounds for the disqualifications.[35] Disqualified bids were ineligible to compete on price and were not considered for a contract award. During CBP round 1, CMS also conducted a postbidding review process through which the agency considered concerns raised by losing suppliers and in some cases, reversed decisions to disqualify the bids of certain suppliers. We found that CMS had not effectively notified suppliers about the opportunity for this postbidding review process. To improve future rounds of the CBP, we recommended in our 2009 report that if CMS decides to conduct a review of disqualification decisions made during the CBP round 1 rebid and future rounds, CMS should notify all suppliers of any such process, give suppliers equal opportunity for such reviews, and clearly indicate how they can request a review. CMS agreed with our recommendation.

For the CBP round 1 rebid, CMS sent notification letters to winning suppliers beginning in July 2010.[36] CMS officials informed us that after the CBP round 1 rebid contracting process is completed, CMS plans to send letters to all disqualified suppliers with the reasons why their bids were disqualified.[37] CMS officials said the letters will explain the process by which suppliers may ask questions and express concerns. CMS officials also stated that in the course of responding to such questions or concerns, if CMS determines an error was made, it is possible that a CBP contract may be offered to the supplier.

[35]By the end of CBP round 1's initial bid review, almost half of the bids submitted were disqualified (3,143 of 6,374 submitted). A bid could be disqualified for more than one reason. Nearly 9 of every 10 disqualified bids (86 percent of the 3,143) did not submit complete financial documentation. Twenty-two percent of the bids were disqualified for noncompliance with accreditation requirements; that is, they failed to receive accreditation by the deadline established by CMS. Two percent of the bids were disqualified because the bidding suppliers did not meet supplier financial standards; that is, in CMS's judgment, they were unlikely for financial reasons to be able to fulfill their contract obligations.

[36]CMS informed us that they sent letters to winning suppliers in July 2010, extending offers to enter into a contract with CMS to provide selected DME. These suppliers must respond to CMS, by either accepting or declining to enter into these contracts. Once CMS has heard from all these suppliers, CMS will finalize the contracts and determine whether there are sufficient numbers of contracted suppliers. CMS officials informed us that they expected to complete this contracting process later in September.

[37]CMS officials told us that there are 11 disqualification reasons for the CBP round 1 rebid.

As required by MIPPA, we will study the CBP round 1 rebid, including, for example, the program's impact on Medicare beneficiary access to items and services and on DME small business suppliers. Our study is to be completed no later than one year after the CBP round 1 rebid's Medicare competitively determined payments are first made, which become effective for covered items and services on January 1, 2011.

Agency Comments

In commenting on the information presented in this testimony, CMS officials stated they appreciated GAO noting the administrative improvements to the competitive bidding process the agency made for the round 1 rebid. The officials further stated that they believe that CMS made many improvements to the CBP. CMS also provided technical comments that we incorporated as appropriate.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the subcommittee may have.

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact

For further information about this statement, please contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

Staff Acknowledgments

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Medicare: CMS Did Not Control Rising Power Wheelchair Spending. GAO-04-716T. Washington, D.C.: April 28, 2004.

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Mr. PALLONE. Thank you, Ms. King, and now we will start and ask questions from the members. It is generally 5 minutes for each of us, and I will start with myself.

My questions are to you, Mr. Wilson. You probably heard before, many suppliers have expressed the belief that winning suppliers will be unable to meet their contract performance requirements, in effect, you know, it happens a lot now with the economy that they offer up a suicide bid just to stay in the program without any actual ability to deliver on their promises or maybe they think they can deliver but they can't ultimately. Have you seen examines of what I call suicide bidding and do you have any protections in place to guard against inappropriate bids?

Mr. WILSON. Mr. Chairman, I don't know that I have seen an example of a suicide bid. We have a process in place to determine whether or not suppliers are qualified, licensed, accredited, meet all the standards required by Medicare. The second part of the process deals with whether or not their bids are bona fide, and yes, we have found bids that aren't bona fide. We do have a process where we analyze, request information such as invoices from suppliers to show, to prove and document that they can meet a certain price and we requested that information and verified whether or not there were what we would term a low-ball bid, unsustainable bid.

Mr. PALLONE. I know you said you have a plan, but as another follow-up, will referral agents, and I guess, you know, would there be any kind of follow-up where people will be able to report problems and, you know, you find out about those problems as opposed to just looking at the plans?

Mr. WILSON. Well, I think that is a very important part of the program. I think the key here for us is ensuring that we have enough qualified, able suppliers in place to provide quality services to our beneficiaries. That is the key to the entire program. Our ability to educate, communicate with folks that are involved in that process like referral agents including physicians, hospitals——

Mr. PALLONE. Social workers?

Mr. WILSON. Social workers, State health insurance programs. That is all part of our communications plan that we will ramp up. We have already started but we will ramp up towards the end of this month when we release the list of contract suppliers. It is a very key part of the program. To the extent that either a supplier or a beneficiary has a concern, we will be educating all of these entities on where they go through direct mail, through documents, Web sites, again talking with partner organizations that deal with beneficiaries so that a beneficiary will know to call 1–800. A complaint would get routed. We would track that complaint. We have an ombudsman program that can deal with that complaint. We have local ombudsman that can——

Mr. PALLONE. And what if there is a shortage, I mean, if there a problem? Do you have the ability to add capacity if shortages arise, you know, like if a contractor fails?

Mr. WILSON. We believe we have offered contracts to more than enough suppliers to provide access to beneficiaries in these nine areas. A core principle in the program with respect to offering contracts is to set a demand target that is very, very high so that we

can guarantee we have enough suppliers. So if a supplier has a problem, maybe we lose one, maybe their number gets revoked, we will still have enough suppliers. If we need to add a supplier, we can certainly go out and offer a contract.

Mr. PALLONE. OK. My second question is more local, you know, referring to my State. In the Medicare Improvement for Patients and Providers Act of 2008, it gave CMS the authority to split metropolitan statistical areas more than 8 million people into separate bidding areas. Now, New Jersey is in one of these very large metropolitan areas that includes New York City, northern New Jersey, Long Island, Pennsylvania, you know, like maybe 20 million people altogether. I think because the geographic area and the number of people is so large, it is essential that the MSA be divided into market areas that better reflect prevailing medical practice, and it is my understanding that CMS has proposed to subdivide this market into five smaller competitive bidding areas. Is that correct, and isn't it true that these smaller areas—well, I want to know is it true, and secondly, if these smaller areas are going to better reflect the differences between southern New Jersey, northern New Jersey, New York. Do you want to respond to that?

Mr. WILSON. Sure. It is absolutely true, Mr. Chairman. We did discuss that issue with our advisory committee. We received advice. We put our proposal in a proposed rule this spring and have received comments and are looking at the issue right now.

Mr. PALLONE. So you have made a decision to subdivide the market?

Mr. WILSON. We have proposed a methodology in a rule to subdivide the market, and we do believe that is the correct thing to do here.

Mr. PALLONE. And how is that being done to reflect the differences, you know, as I said, New Jersey versus New York, north, south Jersey, whatever?

Mr. WILSON. Right. Well, the issue that we are dealing with is really the New York metropolitan area so we are looking at New Jersey counties that are west of the city as one area and New Jersey counties that are immediately south of the city as another area. We also added in Pike County, Pennsylvania, to the western New Jersey counties. I don't think people like that so we will be looking at that aspect of our proposal very closely but we certainly did look at these market areas trying to develop more homogeneous market areas that would better serve suppliers' ability to deal with patients across a smaller area.

Mr. PALLONE. I don't want to take up any more time but I may follow up with some written questions to you about that.

Mr. WILSON. Absolutely.

Mr. PALLONE. Thank you.

Mr. Whitfield.

Mr. WHITFIELD. Thank you. Mr. Chairman, I would like to ask unanimous consent that we enter into the record this testimony from a representative of ConvaTec, a company on this issue.

Mr. PALLONE. Without objection, so ordered.

Mr. WHITFIELD. Mr. Burgess is so fast, I didn't know he had already done it.

Mr. PALLONE. You have got to watch him.

Mr. WHITFIELD. Thank you for your testimony. We appreciate it very much.

Mr. Wilson, let me just ask you, critics of this program have noted that the first effort needed to be terminated, the first bid effort needed to be terminated in 2008. Would you please explain specifically why that was necessary and why CMS believes that the second round will be different?

Mr. WILSON. Well, I can certainly talk to some of the issues and concerns from the 2008 round of bidding that I think we have tried to address and I believe that we have addressed consistently with the GAO's testimony today, but there were a number of concerns, particularly with regard to how the agency communicated information about bidding, the timing of communication that perhaps contributed to confusion about what the rules were. That is something that we have acted to fix in this round. We didn't revise instructions midway through the bidding process this time, as we did last time. I think that was very important to provide a level playing field for all suppliers involved in the bidding. The online bidding system last time, as I mentioned in my testimony, did not work. It was frustrating. Suppliers would enter information, think they saved it, and when they went back it was gone. There is a lot of information associated with the bids and we recognize that was a frustrating process. We fixed that. We did not have those problems this time. Those were legitimate concerns that needed to be addressed. We did not validate licensing up front in the process in 2008 so we looked to verify licenses afterwards, after the bids were submitted. What that may have led to is speculative bids being submitted by certain suppliers that maybe came in from out of state. This time we said you need to have your licenses up front. They have to be in order and all of your other qualifications in line such as accreditation so that that tended to favor local suppliers since they really just needed to have—local suppliers tended to be the ones that had local licenses and so those were the ones that I think benefited from that policy.

I think the scrutiny that we placed on bids this time was more, that we heard a lot of concerns about, one, whether they would be too many low-ball bids coming into the process. Again, we looked at that very closely, revised our process this time. We requested more information in terms of an explanation of suppliers' bids where we found them to be aberrantly low. We looked very closely at some of the invoices that were provided, and when a supplier could not justify the level of their bid if it was low, we would discard that bid.

Mr. WHITFIELD. Let me—I appreciate your responding. You did a very good job of covering some areas but let me ask you another question here. I was reading an article recently about a provider in Tennessee that on this most recent round submitted a bid for all areas in the wheelchair category, and only about 10 percent of his business was really related to these wheelchairs, and he evidently was offered—he won the bid in basically half of those 10 areas, and he deliberately submitted a low bid according to the article I read, and when you all offered him the contract he refused the contract. Are you aware of that particular situation?

Mr. WILSON. Yes, Congressman, I am aware of that situation. I have looked into it. At the outset I would say I can't talk about specific information in that supplier's bid. We consider bid information proprietary. I will say that everything in that article is not accurate.

The other thing that I would say is, looking at the article the supplier was very clear that he felt his bid was a fair price compared to the quote, unquote, cost of goods. In fact, that leaves a higher gross margin and a lot less labor than your average complex rehab chair. So he thought he had a profit in there and that that was a good bid.

Mr. WHITFIELD. Even though he——

Mr. WILSON. Even though he refused it. The other thing that he said is that the primary reason he didn't accept it was because that particularly after round two utilization will drop substantially. Marketing and advertising drives utilization, it drives demand in reimbursement. It isn't going to allow for $800 to $1,000 per chair for marketing and advertising anymore.

Mr. WHITFIELD. But I think the concern is that you have someone like this that is really not in that business and he does a low-bad bid and then in the matrix as they look at final bid prices, it does put at a disadvantage a lot of the local suppliers. At least there is the concern for that, which may be valid or may not be valid. But my time is expired, so thank you.

Mr. PALLONE. Thank you.

Chairman Dingell.

Mr. DINGELL. Mr. Chairman, thank you for your courtesy.

Ms. King, you allude to a situation in your testimony where I am concerned. Would you say the DME program as currently constituted is unusually conducive to fraud as compared to the rest of Medicare? Yes or no.

Ms. KING. Yes.

Mr. DINGELL. Why do you feel that way?

Ms. KING. Congressman Dingell, I think there are several reasons for that. There are some parts of Medicare including DME where the barriers to entry have been historically low so that it doesn't take a lot to get into the market and it has made it easier for unscrupulous providers to enter into the market, to start billing Medicare, and then when people start to catch up to them to close up shove and move on to somewhere else.

Mr. DINGELL. Thank you. Please submit for the record what additional steps must be taken to see to it that we have completed the addressing of the problem of fraud with regard to durable medical equipment.

Now, Ms. King, I want to compliment you and GAO. You know the respect I have for your agency.

Ms. KING. Thank you.

Mr. DINGELL. CMS has instituted many new requirements outside of the DME competitive bidding program with more help combating waste, fraud and abuse will come as a result of health reform. But even apart from that, CMS argues that competitive bidding will reduce fraud. In your testimony, you note that competitive bidding has the potential to reduce Medicare expenditures by

using market forces. Question: Do you think that it might also reduce fraud amongst DME suppliers as CMS claims, yes or no?

Ms. KING. Yes.

Mr. DINGELL. Now, OIG draws a connection between overpayments and fraud. Essentially they say honey draws flies. Do you agree that there is a link between overpayments and fraud?

Ms. KING. I don't think that we have done work directly on that point.

Mr. DINGELL. Now, these questions are for Mr. Wilson or Ms. King. Changes have been made since round one. You have indicated in your testimony there are many problems reported during the initial round of competitive bidding. GAO documented unclear bidding instructions, poorly performing bidding software and inadequate supplier education before commencement of the bidding. MIPPA mandated many changes in the program that have been adopted in round one re-bid including the requirement that CMS allow suppliers a chance to complete their financial documentation at a date certain for quality accreditation. Question: Has CMS made other changes to facilitate fair competition in the round one bid? Yes or no.

Mr. WILSON. I will answer, Congressman Dingell. Yes, I believe we have.

Mr. DINGELL. Ms. King?

Ms. KING. We haven't seen the final results yet so I think that we will reserve judgment until we see that.

Mr. DINGELL. Would you review these questions and see whether they are being fair to the bidders, and please report to the committee for inclusion in the record?

Ms. KING. Yes, we will.

Mr. DINGELL. Now, one of the problems GAO documented was that many suppliers were disqualified due to incomplete financial documentation, a fact that they were often not aware of. Based on your experience with regard to the round one re-bid, do you believe that this problem of suppliers being disqualified in large numbers due to incomplete documentation has been fully addressed?

Ms. KING. We haven't seen the results yet but I do think that the new bidding system has the potential to really help with that because it signals supplies when documentation is not provided or is incomplete.

Mr. DINGELL. Mr. Wilson?

Mr. WILSON. I believe in answer to your question, Congressman, that the answer is affirmative. I can provide——

Mr. DINGELL. Would you please each review that and tell me what of the questions of basic fairness have not been properly and fully addressed by CMS for submission in the record?

Now, another issue raised during MIPPA was again one of fairness. It seemed unfair that because bid instructions were changing, early bidders had to spend extra time to make sure their bids were still appropriate, and it seemed unfair in the GAO report that some suppliers were given a chance to review all their disqualifications while others were not. First of all, one, Mr. Wilson, is that true?

Mr. WILSON. It is true that bid instructions and additional information were released during the bid window in 2007, and so yes, it would be true.

Mr. DINGELL. OK. Has that been corrected?
Mr. WILSON. It has been corrected.
Mr. DINGELL. Are you satisfied with that?
Mr. WILSON. I am satisfied.
Mr. DINGELL. Ms. King, what are your responses to those questions?
Ms. KING. Yes, we do think it has been corrected. With regard to the disqualification process and the review process, that has not occurred yet with the round one re-bid so we don't know what the outcome will be yet.
Mr. DINGELL. Is there anything that has to be done to assure that the unfairnesses that we are discussing here have been properly addressed?
Ms. KING. CMS has told us that they intend to provide notice to all suppliers about the reasons why they were disqualified and give them an opportunity to express an opinion.
Mr. DINGELL. I think we are agreed that these matters must be conducted fairly. Would you submit to us for the record any matters which need to be addressed by CMS to assure fair bidding?
Ms. KING. Yes, sir.
Mr. DINGELL. Now, again——
Mr. PALLONE. Mr. Chairman, just to note, you are a minute and a half over.
Mr. DINGELL. I am sorry, sir?
Mr. PALLONE. Just to note, you are a minute and a half over. If you want, you can continue a little bit but——
Mr. DINGELL. I ask that I be permitted to submit those questions. Mr. Chairman, may I just ask this one important question to each of the witnesses?
You have all seen H.R. 6095, the bill I have introduced. Would you please tell me whether or not you have any concerns about how that will adversely impact the cost to the government of the program we are discussing? You may submit that for the record.
Mr. Chairman, I yield back the balance of my time, and I thank you for your courtesy to me.
Mr. PALLONE. Thank you, Chairman Dingell.
Next is the gentleman from Pennsylvania, Mr. Pitts.
Mr. PITTS. Thank you, Mr. Chairman.
Mr. Wilson, you claim that the overall savings to Medicare and beneficiaries will total $28 billion over the first 10 years without compromising quality or access. Can you explain why you are so confident quality and access will be maintained at current levels?
Mr. WILSON. Well, we will have a program in place to ensure quality, provide oversight, communicate with beneficiaries, communicate with beneficiaries, communicate with others involved in their care. We will have complaint process if we have of concerns. We will have a process in place to act swiftly to address those concerns. There are certain underlying features of the program which address quality, requirements on suppliers in terms of accreditation and quality standards, other parts of supplier standards which apply and with the competitive bidding program comes a more focused oversight effort on the suppliers that are involved in the program and have contracts. So we believe we have the mechanisms

in place, the infrastructure in place to deal with individual beneficiary issues and more systemic beneficiary issues.

One thing that is different in the program from 2008 is, we will be doing active claims surveillance on the claims as they come in to be able to see who is providing the care, who is getting the care and whether or not there are any issues or concerns. We can look and see things like are there more emergency visits, are there longer hospitalizations, are there some of the kinds of quality problems that we might be concerned about. So we will be looking very closely and we will have a plan in place and the resources in place to deal with problems as they arise.

Mr. PITTS. What beneficiary protections are contained in the program?

Mr. WILSON. There are a number of important beneficiary protections. I think one of the key ones is something that was provided in the law. It is called grandfathering. So for many suppliers and many beneficiaries, the existing supplier, even if they don't win a contract, they can stay in the program. The last time in 2008 we saw that over 90 percent of oxygen suppliers—and of course oxygen patients are the ones that we would be most concerned about in terms of any quality adverse outcomes. So we expect that there will be a lot of grandfathering. We have selected a number of suppliers to be contract suppliers so that beneficiaries will have choice. If they don't like care somewhere, they can go somewhere else. We have a safety net provision provided by Congress called the physician authorization provision. If the physician for the patient feels a specific brand or mode of treatment is required, that has to be provided under the program by a contract supplier. Anti-discrimination provisions—we require suppliers under the program to provide the same treatments, the same items and services, brands, models to their Medicare patients as they do for their private patients. We have other provisions which require transparency, so we will be publishing and updating quarterly all the brands and all the models that each contract supplier provides so that beneficiaries, caregivers, referral agents can look and see what types of products and brands they want and sort of vote with their feet and go to suppliers that provide what they need, and that also creates competition around the quality of the items and services provided. And then as I mentioned——

Mr. PITTS. Go ahead.

Mr. WILSON. And then as I mentioned, the oversight and monitoring efforts that we will have in place.

Mr. PITTS. Now, your testimony speaks of protections for small suppliers. What are these protections and how were they created?

Mr. WILSON. The law asks us to put in place a program that allows suppliers the opportunity to participate in the program. We feel like we have done a lot more than that. We worked with the Small Business Administration to put a place a definition of a small supplier, which is something less than the definition or a lower threshold than a small business because many suppliers are very small mom-and-pop entities. We built some policies around that definition. We actually have what we call a 30 percent target, really a set-aside where we make sure that in every auction, in every bid in an area for a product category we insert 30 percent

of the suppliers meet that definition, and if they don't, we add small suppliers.

We found that with respect to the current contract offers that we have made, we have exceeded that target. It is almost half, 48 or 49 percent are small suppliers that meet that definition. We allow small suppliers to band together as a network to meet all the requirements under the bidding program. Those are just a few of I think the most important provisions.

Another key one I will mention is that we have the way the policy works, the way the bidding program is structured results in multiple suppliers so we try to select lots and lots of suppliers. Ninety-two oxygen supply contracts are offered in Miami. I think 42 wheelchair contracts offered in Riverside. We try to make sure there are lots of suppliers so that beneficiaries have choice, more suppliers can participate. That also has an upward effect on price.

Mr. PITTS. My time is expired. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Pitts.

Next is the gentlewoman from Ohio, Ms. Sutton.

Ms. SUTTON. Thank you, Mr. Chairman.

Mr. Wilson, would you agree with me that it is absolutely important to cut out waste, fraud and abuse and that we must do so through a fair process?

Mr. WILSON. Absolutely.

Ms. SUTTON. One that will permit patients to continue to access appropriate and quality care and services?

Mr. WILSON. I do.

Ms. SUTTON. OK. Is CMS monitoring whether beneficiaries in the bid areas will be able to continue to access the same brand products and the level of services, particularly for beneficiaries with chronic conditions and needs?

Mr. WILSON. We certainly will be collecting that information, asking suppliers to update it quarterly and publishing it.

Ms. SUTTON. OK. Mr. Wilson, as you are going forward with the next bidding process—actually let me just direct this to anybody who has information. We have heard a lot, and we have heard some questions that reflect it. There are many reasons why bids are low but industry is saying that out of the area and inexperienced companies were allowed to bid and set area rates, then withdraw from the bid process with no repercussions, leaving the area and local providers to deal with unrealistic bids, and I guess the question would be, why would you allow out-of-area companies with no accountability to bid in the first round areas, and after they withdraw then keep those illegitimate bids in the matrix for crafting new bid rates, if that is indeed what happened?

Mr. WILSON. Sure, I can provide some information I think to address this issue, Congresswoman. I think during the first round in 2008, 95 percent of contract offers were accepted. I think while we are not done the contracting process, we expect to see something similar so most contracts are being accepted. I think the other thing that I would say is that 72 percent of contract offers went to providers, local suppliers that provide the product category for which they bid. A further 11 percent were local suppliers that maybe provided a different product category but local suppliers and a further 12 percent for a total of 95 percent were maybe out-of-

area suppliers but were experienced in that product category. So I think that we see is overall 95 percent of the suppliers being experienced meeting all of our requirements. We have certainly never had requirements in Medicare that say a particular provider can't expand from one State to another State or one city to another city, and we didn't see an ability to place such restrictions on this program here.

Ms. SUTTON. Well, there are a lot of concerns and of course you have heard many of them expressed here today, and whether it is the small suppliers, I will say that it is my understanding that the Cleveland Clinic, for example, bid below the allowable price and didn't win one contract. In January they will no longer be able to provide services and patients will have to wait until the DME provider that won the bid will be able to provide it. So you can understand that there is a lot of concern out there about how this is actually going to play out in the lives of the people that we are so honored to serve.

I guess one of the things, going back to—we know that CMS is prepared to survey consumers regarding the level of service and quality of care changes and the round two of the bid process of course is scheduled to begin in the spring of 2011, but how can the surveys provide a quantitative analysis in order to determine the success of the program and to identify any shortcomings and how quickly will the surveys be completed and on what frequency?

Mr. WILSON. I would have to get back to you with respect to some of the details of the survey. We will be conducting a consumer satisfaction survey. We have already done a pre-implementation survey to provide a baseline. So I think we will be moving forward quickly. I will provide to you specific information on when that follow-up survey will occur. But I think there are, you know, many other things that we will be doing in terms of monitoring. We will be collecting information from Medicare 1–800, from our ombudsman program so that we can review complaints, analyze complaints to see if there are systematic problems. I already mentioned the active claims surveillance that we will be doing. So we are really trying to look on a broad basis using a number of different tools to penetrate some of the issues and concerns.

Ms. SUTTON. Let me just follow up on that line real quickly here. What will happen if CMS identifies a reduction in quality and service? Is there a particular change that will trigger CMS's intervention? I mean, it is a very uncertain future.

Mr. WILSON. I guess that could take many, many forms, and to the extent that it was a concern with respect to a particular supplier not meeting the quality standards or doing something in conflict with the quality standards, that may call for a certain typed of targeted intervention. If we found that there was a broader base concern, we would have to consider what that is, what the circumstances are and move swiftly to take appropriate action. So without sort of knowing what that is, it is hard for me to say.

Ms. SUTTON. I thank you, and Mr. Chairman, I have additional questions I will submit for the record.

Mr. PALLONE. Any member can submit additional written questions and we will ask you to get back to us fairly quickly if you can.

Next is the gentleman from Texas, Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman.

You know, as I sit here and we have this hearing and if I take myself back to July of 2008 when we passed MIPPA, you know, as I recall, we passed that under suspension. I don't think we had a markup here in the subcommittee. I don't think we had a markup in full committee on the delay of the competitive bidding program and it just underscores how when we circumvent the normal process, how harmful it is. It is harmful to businesses, it is harmful to patients and even the federal agencies are left trying to make sense out of what Congressional intent was. So while this committee probably didn't play a role in allowing MIPPA to come to the floor without any discussion under suspension, it was wrong, it was a mistake, and I think going forward this committee needs to assert its authority at the subcommittee and full committee level.

I am very grateful to our witnesses for being here today. Mr. Wilson, I know that you have heard from several members that here we are, now we have the 6-month anniversary of the Health Care Act coming upon us next week. The Secretary is going out with some re-education that she talked about in the newspapers last week. We haven't heard from her. I know she can't just show up to this committee. She has to be invited. I have here a copy of a letter. It is actually the second letter that Mr. Barton and I have submitted to Mr. Waxman asking him to invite the Secretary to come to the committee. I would ask you today, sir, would you be kind enough to carry a copy of my letter to Mr. Waxman asking him to invite the Secretary so that she may be prepared for that invitation when I hope it eventually comes? Can I ask you to carry this to the Secretary, sir?

Mr. WILSON. Absolutely.

Mr. BURGESS. Thank you. A couple of questions then for you. You know, it appears as we go through this and hearing your testimony, some of these competitive bidding contracts, I mean, they are going to be—the amount of money coming in may be substantially reduced, and that may be entirely appropriate, but have you at HHS done any studies as to the market feasibility of removing this amount, these amounts of dollars from the business models of these companies that are the suppliers?

Mr. WILSON. We have certainly examined the pricing structure and some of the business models closely.

Mr. BURGESS. So have you done studies as to the market feasibility?

Mr. WILSON. I don't think we have done what I would call or describe as a market feasibility study the way a corporation might conduct such a study who wants to launch a product.

Mr. BURGESS. But the only reason a corporation would do it is because they want to be able to be competitive and provide the good or service to the person, the customer, the end user that needs it so it would make sense to do that. Well, let me just ask you, have you done any studies on how this would impact patient access to any of these supplies? We have heard several people mention that today, Cleveland clinic, I think Mr. Hall brought it up. Have you looked into that?

Mr. WILSON. Yes, I think that we know is that many of the products through a number of different studies by GAO, OIG and our

own analysis of some of the information that we have now from suppliers that many of the items under the current fee schedule are very overpriced.

Mr. BURGESS. And I don't disagree with that at all, and shame on us as a committee, shame on the federal agencies for not having addressed this problem sooner.

Now, Mr. Levinson, since you are here, and I am so glad you are here, I don't really understand why you are here but I am glad you are here because we need to have this discussion, and in fact, I hope, Chairman Pallone, that you will convey to Mr. Waxman that it would be good to get Mr. Levinson and perhaps some of his counterparts at Department of Justice to come to our oversight committee and talk to us about this in some detail because in your written testimony you detail the importance of oversight, and honestly, it has been lacking over the last 3–1/2 years and I just hope going forward we can get that—we can have that happen. I see, you know, the television stories repetitively back in my home, basically the Dallas-Fort Worth television market, a gentleman comes home and finds a wheelchair in his living room they have never asked for. He is fully ambulatory and he can't understand why he has a wheelchair, and the reporter unraveling this Gordian knot comes back to the fact that he went someplace for some blood test some 6 or 12 months before. They got his billing information and through a convoluted series of different providers, now he ends up with a wheelchair in his house and he doesn't know what to do with it because his house is not able to accommodate a wheelchair and he doesn't need one. So these types of stories just drive people crazy, and in my discussion with your counterparts in our area and the Department of Justice, one of the problems that they have is the lack of federal prosecutors. When you guys develop a case and bring a case, the lack of federal prosecutors to then pursue that has been very, very difficult, and in fact, there was one foreign national who had multiple provider numbers. One provider number was shut down—and this was a home home, not a DME provider—but one provider was shut down but they kept cutting checks to the same person with different provider numbers and they all went to the same post office box. Have you got no mechanism within HHS to control for that seeming oversight, that we just keep sending checks to a post office that we know the lady's going to jail and we're sending checks to that same post office box? Are you working on that?

Mr. LEVINSON. We certainly are working on it and we know that CMS is also working on it because it is extremely important to get the information technology right in order to be able to be, if not the head of that criminal element, at least able to quickly try to remedy that kind of problem, which has plagued the system for many, many years.

Mr. BURGESS. With all due respect, sir, sometimes it seems like we are not even fielding a team to oppose them. We invite them. We beg them, come take this money from us, we have too much, please take it. And we have heard it over and over again and it comes up in stories in our districts, and this is what is driving people crazy. We have got to be smarter. I mean, you referenced that perhaps there is an element of organized crime. We need to be

smarter in dealing with that and the punishment needs to be swift and sure. We spend all this money going after mom and pops that are doing the right thing and taking care of our patients and we let the criminals escape.

I realize I have gone over. Thank you, Mr. Chairman, for your indulgence. I will yield back.

Mr. PALLONE. Thank you.

Mr. BURGESS. Unless Mr. Levinson wants to respond to that.

Mr. LEVINSON. Well, I think one of the most promising efforts just in the last couple of years has been the Strike Force effort that has developed between our Office and the degenerative joint disease with the help of CMS to close down fraudulent DME operators, especially in south Florida. The program is effective in southern California. We have important operations around the Gulf area. So I think there is an increasingly positive record of being able to really enforce the law when it comes to DME fraud that is returning millions and potentially billions to the trust fund. So this is actually a very important turnaround for the program and I would be happy to provide more detailed data.

Mr. BURGESS. I would be grateful for that.

And Mr. Chairman, I would just reiterate my call that you ask Chairman Waxman to convene a subcommittee, an oversight——

Mr. PALLONE. I am not going to suggest anything to Chairman Waxman but I would say——

Mr. BURGESS. It is your duty.

Mr. PALLONE [continuing]. I would appreciate if you would get back to us further on that question that Mr. Burgess asked.

The next is the gentlewoman from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. I think that this has been quite instructive, both the questions of the members and the answers and the testimony of the panelists, so thank you to Ms. King, to Mr. Wilson and to Mr. Levinson.

Mr. Levinson, I was struck by many of the things you stated in your oral testimony, particularly the idea that overpayments, which we try to eliminate because they represent waste on their own terms, actually contribute to and exacerbate fraud. If we pay too much for something, we not only waste money on that purchase, I think we are at the same time creating a magnet to attract bad actors. I mean, we can't forget as we are concentrating on the dollars that are abused and the fraud that we know is in the system and how important it is to fight it that there are very honest, good people that own small businesses and do a very good job. I don't think that is what this hearing is about. That is certainly not my intent, but I am struck by the amount of money that you said in your first few sentences that. Was it $20 billion or $10 billion a year? I wanted you to restate that because I think everyone needs to hear that number again.

And here are many questions to you. Can you give us any examples of the nexus between overpayments and fraud? And I think that you can probably do that off the top of your head. And in your testimony, your testimony mentions wheelchairs and negative-pressure wound therapy pumps. You say in your testimony that competitive bidding by connecting prices paid in the program to market prices could actually help address this problem. So can you elabo-

rate on that, and I think that there is something that the subcommittee needs to re-appreciate all over again, that this new process that is being set up estimates that there would be $20 billion in savings over 10 years, $20 billion. I don't know the last time anyone ever saw that in their checking account. But those dollars, those precious dollars would be plowed right back into Medicare to offer direct services to seniors in this country. So we are talking big numbers and things that are really significant. So would you like to answer my questions?

Mr. LEVINSON. Well, if I can please return to the numbers that I started off my testimony with, we are talking about approximately 11 million beneficiaries who have occasion to use DME good over the course of the year at a cost to the program of about $10 billion. What I said thereafter was that CMS estimates that about half of the DME claims were paid in error. Now, errors——

Ms. ESHOO. That is really stunning.

Mr. LEVINSON [continuing]. Have multiple causes. There isn't one—this isn't necessarily overt fraud, and it is important to understand that we are talking about a failure very often of documentation, and the problem with not getting accurate documentation of course is that you really can't account for exactly what was provided and for what reason and what appropriate cost. So documentation is really the lifeblood of the program, and when we are talking about an error rate that high, that does suggest a serious systemic problem just being able to——

Ms. ESHOO. I would certainly say so if it represents 50 percent. There is something really wrong with whatever system is there.

Mr. LEVINSON. Yes. The nexus of fraud with overpayments is that if you have too much of a disparity between acquisition costs and the price, that actually does provide an incentive for those masquerading as legitimate, genuine DME suppliers as they come into the marketplace, and indeed, we do have a lot of pricing reports that indicate that there is a significant disparity between what CMS allows and what the actual acquisition costs or products like power wheelchairs, pressure wound therapy pumps, home oxygen equipment, we do have a body of work indicating that there are serious disparities that CMS needs to remedy and in many case hopes to remedy I think as a result of this program.

Ms. ESHOO. Thank you very much.

I think, Mr. Chairman, in this competitive bidding process that for the businesses that provide these services and equipment, they need consistency, they need clarity and they need to be able to participate in a fair way. They need to know where they stand and the process needs to be a very clear one, but make no mistake about this, I think the overriding issue here is, we do the right thing and in the right way, that this represents billions of dollars. This isn't any small thing.

So I especially want to thank the OIG for the exceptional work. I think every Member of Congress should really read your report. It is outstanding. Thank you very much.

Mr. PALLONE. I thank the gentlewoman. I agree wholeheartedly with your last comments there. Thank you.

Mr. Hall is next.

Mr. HALL. Mr. Chairman, thank you.

I join the parade as the gentlelady from Florida who asked you to take another look, Mrs. Eshoo that I have served with for many years here and I have very rarely ever found on the wrong side of anything, talks about a fair process and the bad actors. I would like to ask the GAO and OIG—I think that is Ms. King and Mr. Levinson—what are you doing and what is your opinion on the fact that Medicare plans to reimburse portable oxygen systems at an average of $21 a month for as many fills or refills that the patient requires and wholesale cost with the highest volume discounts to just a liquid oxygen refill, not including equipment is $30 more than what Medicare proposes in their single payment amount for portable oxygen? What is your opinion on that?

Ms. KING. Can we get back to you on that, sir?

Mr. HALL. You have no opinion?

Ms. KING. I would have a more considered opinion if I had time to look at it more carefully.

Mr. HALL. Will you do that?

Ms. KING. Yes, sir, I will.

Mr. HALL. To Mr. Wilson, I would like to ask you, how can you justify a $21 reimbursement for the portable liquid oxygen system when the cost to fill the liquid system is at least $30 more than what you reimburse? Do you want to look at it some more too?

Mr. WILSON. Well, I think what I would say, Congressman, is that we have looked pretty closely at oxygen equipment. We looked at the OIG reports and we looked at what we have been paying, and you can find this equipment for a lot less than we pay. If you look at our overall payments in oxygen in terms of the monthly amounts, we are paying excessively for oxygen, and I think the bids demonstrate that. And I would be happy to provide more-specific information about the prices that you are quoting. I just don't have those prices in front of me.

Mr. HALL. That is fair enough. We can always ask you for them by letter and you would respond, wouldn't you?

Mr. WILSON. We would be happy to submit them to you after the hearing.

Mr. HALL. You have always claimed, I think, that you perform due diligence on providers and have assured that bidders are financially qualified. That is necessary, isn't it, in your opinion?

Mr. WILSON. Yes, certainly.

Mr. HALL. And you have problems with contracts, the out-of-area companies are companies that have no experience?

Mr. WILSON. I don't think we saw a lot of those companies bidding in this process.

Mr. HALL. You spoke in your opening remarks of smooth transactions and transitions and realistic bidding. You did state on the record that 30 percent of the bidding companies had questionable financials. You said that, haven't you?

Mr. WILSON. I did not.

Mr. HALL. You did not say that?

Mr. WILSON. That quotation I have seen several times over the last few days. It is different in every version, and I would like to submit a statement for the record. I could tell you what I was referring to if you like, sir.

Mr. HALL. I would like to hear anything. I am under the impression that you said that, but if you didn't say it, what did you mean to say——

Mr. WILSON. What I was talking about——

Mr. HALL [continuing]. On the record about bidding companies with questionable financials, because I am also told that you allowed them to proceed through the process, and that seems to me to be a disregard for your own directives, and if that is what you call a smooth transition, why, we have a different opinion on what a smooth transition is.

Mr. WILSON. Well, that is right.

Mr. HALL. And a lot of other people must, because my mail has been flooded with information on those things.

Mr. WILSON. I think you would find, sir, that I probably agree with your position. That is certainly not what I said, so it is inconsistent with my view and my statements.

Mr. HALL. OK. You have offered contracts to out-of-area companies and you have offered contracts to those with little or no experience, have you not, providing competitively bid items and services?

Mr. WILSON. Well, the information I was able to provide today, sir, is that about 72, 73 percent of all contract offers went to experienced local suppliers, those with experience in the product categories. Another 11 percent went to experienced local suppliers that may have provided a different product category. Another 12 percent went to suppliers that were experienced in the product category but came in from the outside area. That leaves about 5 percent that I don't have information on. I expect a lot of those are mail order diabetic supply outfits that are set up out of state somewhere and because they operate through the mail.

Mr. HALL. I ask also of the GAO, it is my understanding that you have done studies on wholesale purchase costs for oxygen concentrators but the question is, have the agencies done cost analysis on the other oxygen systems or any other oxygen system that patients are required to use for their daily living? Have the agencies done analysis on the cost to provide portable liquid oxygen systems that are necessary for patients that want to leave hospitals or visit their doctors or travel outside their bedrooms or maintain employment? Have they done studies on that?

Ms. KING. We have some work on oxygen payments that is currently underway and hasn't been released yet. We would be happy to provide you with that when it comes out. And if that doesn't answer your questions, you know, we could have further conversations.

Mr. HALL. You are good on the word "some" there. How many is "some"?

Mr. PALLONE. Mr. Hall, we will take that question but we are about a minute and a half over. So if you will answer his question——

Mr. HALL. Then I will yield back the balance of my time.

Mr. PALLONE. No, we will let Ms. King answer that one.

Ms. KING. I didn't understand his question, sir. If you can repeat it, that would be helpful.

Mr. HALL. No, that is all right. I will write you a letter and ask for that information, and I don't want an answer of "some" some-

thing. I would like an answer on the numbers if you have them because you know how many letters you have, you know how many inquiries you have made of Mr. Wilson, and his answer I think was some letters were written. I will clarify that in letters to you, and I thank you for your time.

Ms. KING. I will get back to you.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Mr. Chairman, and thank you to the witnesses very much for your helpful testimony.

The benefit of having durable medical equipment suppliers in local communities is that the companies and their staff are familiar with patients in their neighborhoods and are accessible for patients and their families in the event that they need assistance or service for their equipment. So a lot of the frustration you hear comes from all across the country in these small businesses that aren't the fraudulent companies but have been working very hard and providing good service, and it is just frustrating in this transition to competitive bidding to see contracts offered to out-of-area companies that may have little or no experience with durable medical equipment and services and have no familiarity with the area of service or direct access to patients that rely on their equipment, and will this be cost-effectiveness in the long run, and what I am hearing you all say is that we are going to monitor it, you are going to wait and see.

Another concern is that there have been many complaints that the financial vetting process used in the competitive bidding process allows bankrupt companies or companies facing bankruptcy to win bids at rates 30 to 40 percent less than current reimbursement. Please explain this to me. What kind of financial vetting process do you have that allows bankrupt companies to win bids at 30 to 40 percent less than current reimbursement while you are also awarding bids to viable companies but they are saying that they are going to be subsidizing the patients but it makes sense for them to try to win these contracts because this competitive bidding process is so unpredictable?

Mr. WILSON. At the outset, I would just say, Congresswoman, that I am not aware of any bankrupt companies winning contracts. I know there was some discussion in the trade press about a particular company that had a high debt talking about the potential for reorganization several years ago. They may have been considering reorganization. They may have been trying to pressure their creditors to give them a better deal. I don't know. We do know that we looked carefully at their financials. We used the same type of financial ratios that banks and other financial institutions to use the viability of an entity. This falls under our financial standards. It is the reason why we collect the documents such as tax records, credit history and things like that. So we did look at all those things for every——

Ms. CASTOR. OK. I am going to submit this information that was provided to me about the company in bankruptcy, and if you would take a look at it and respond back, I would appreciate it.

Mr. WILSON. Absolutely. Thank you.

Ms. CASTOR. And then one of my colleagues said when we are going to get smarter about health fraud, and I thought it was interesting because right now we are in the implementation phase of the new health care law that contains numerous anti-fraud provisions that will assist CMS and the Office of Inspector General and the Justice Department in identifying abusive suppliers and fraudulent billing practices including the new authorities to screen providers before they enter the program, the new requirements that physicians ordering DME be enrolled in the Medicare program, new data-sharing and data collection provisions, enhanced penalties for fraudulent providers and new funding to identify preventive and punish fraudulent providers. Where are you now in the implementation phase? What is your timetable for these provisions?

Mr. WILSON. Those provisions fall within our Center of Program Integrity. I work within our Medicare fee-for-service policy component. I would be very happy to reply or respond for the record to you on those issues.

Ms. CASTOR. Because certainly a lot of these new requirements to root out the fraudulent practices in Medicare must be taken into account in this DME transition to competitive bidding.

Mr. WILSON. Well, I think they are absolutely important, I agree. There is a number of things that are required by the new law which will act to root out fraud here dealing with some of the issues that the Inspector General mentioned already in terms of documentation for claims. There is a new requirement for face-to-face visits with physicians to document physician orders for DME. I think that is going to be important.

Ms. CASTOR. We have to do this because the bad actors in DME are painting a picture all across the country that anyone that is in this business is involved in fraud. That is why I think it is absolutely—and coming from Florida, I am particularly sensitive of especially the Tampa Bay area that is very different from Miami and south Florida and oftentimes a lot of small businesses in my area have to bear the burden that someone says I am a Medicare provider in Florida and people wonder, and that is not fair. Thank you.

Mr. PALLONE. Thank you, Ms. Castor.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I apologize for not being here for the opening testimony and statements. It is a busy time for many of us. I appreciate Ed Whitfield sitting in for me.

First, Mr. Chairman, for the record I have two submissions that I would ask. One is from our colleague, Mr. Langevin, which you have seen, and also from the Diabetes Access to Care Coalition.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. SHIMKUS. Also, I don't know if it is appropriate but I see our colleague, Nancy Johnson, in the hearing room, and she has worked diligently in her time on Ways and Means in this field, and Nancy, it is good to see you. You are not hiding from me. I see you there.

I am going to talk macro and then I am going to talk micro. The macro debate is this—and I am glad some comments were made

about the health care law because everybody knows, I am a competitive market-based conservative. Now, we are the policy people. You all have to implement. In the private practice, auditing of payments happens for the most part before the checks get sent because the private sector doesn't want to lose the money and fraudulently spend money, and sometimes our constituents have terrible times because they are fighting with the auditors of the insurance companies or the HMOs begging for the check to be sent. In our system, we send the check. We are fee-for-service folks. We send the check, and we can send the check for multiple years to one single mailbox for millions of dollars and every candidate who runs for federal office when they talk about the funding problems of Medicare, what do we say? We are going to clean up waste, fraud and abuse, and what do we point to? We point to this. And that is the frustration, and I think it is a bigger problem than just getting our t's crossed and our i's dotted. It is a fundamentally different system of a one-payer system of fee-for-service that only worries about the expense after the fact versus someone who is watching the check and making sure the check is going to the right place before. It is a government model versus a private-sector competitive market model. That is the macro debate and that is kind of why we are here. But that is our discussion. You guys implement, and so we appreciate the challenges that you have.

And also, you know, just adding to Dr. Burgess, we do have a new health care law that is kind of going down in that direction and it would be good for the Secretary to come talk to us, and now I am on record at every hearing asking for that so I will do that now and then I will do that this afternoon and I will continue that record of saying, you know, it is about time we at least had someone who wants to talk about this law because no one wants to, and I would pretty much argue that during the whole 6 weeks of break no one was talking about it. Well, we were talking about it but no one else was really defending the law out in America.

Now to a micro issue which I know is important. It is important to the disabled community, it is important to some producers, so I am going to go to Mr. Wilson. Mr. Wilson, do you believe that a code that does not represent a distinct, homogenous group of products should be included in competitive bidding?

Mr. WILSON. As a general matter, yes, it should be included.

Mr. SHIMKUS. The final rule for competitive bidding stressed product categories would include items intended for similar medical condition. Do you believe that the intended uses of mobility and wound prevention and treatment are similar medical conditions?

Mr. WILSON. If they are related products, yes.

Mr. SHIMKUS. Well, you should know the direction by which I am heading, a litany of groups from the disabled veterans to the Christopher Reeves Foundation have raised concerns over seat cushions and mobility equipment being lumped in the same category and then you exacerbate skin type injuries and abrasions and really huge problems because they are in a unit versus separate. Given—and I don't think that is really debated. I would think that you could ask the physician community and I think you can ask the disabled community, I don't think this is a—I have seen them.

If that is the case, shouldn't we reconsider the inclusion of these type of products in the future?

Mr. WILSON. I don't personally see a reason for reconsidering their inclusion. That said, we have not posted, made a decision on what items will be included in round two. But for this round, I think it is important that they be included. We think that the prices are excessive——

Mr. SHIMKUS. Let me end up. The letter from Mr. Langevin, one of our colleagues, one of the really well-respected members who has led us in a new era of understanding the disabled community I think has a very strong position, and I would hope that the Administration would listen to him and other people who feel that this policy is harmful and I would suggest we take a look at it again, and with that, Mr. Chairman, I yield back.

Mr. PALLONE. Thank you.

Mr. Braley.

Mr. BRALEY. Thank you, Mr. Chairman.

Mr. Wilson, I am going to start with you. I wasn't here when competitive bidding was made law, but isn't it true that there is a lot of ways that you can address the issues of waste, fraud and abuse that wouldn't involve competitive bidding?

Mr. WILSON. There are certainly many ways for addressing this problem.

Mr. BRALEY. And in fact, in Mr. Levinson's written testimony that he has provided to the committee, he documents a lot of the work that the OIG has done to try to address the enormous problem we have in health care delivery with waste, fraud and abuse, and at the conclusion of his recommendations, he notes, "It is critical that these and other program vulnerabilities be addressed be it through competitive bidding or otherwise," and that "otherwise" is a huge sector of health care delivery that involves diligent oversight and management. You would agree with that?

Mr. WILSON. That is certainly one of the areas that we would need to pursue in order to solve this problem.

Mr. BRALEY. Has CMS to your knowledge done an analysis of the impact of the competitive bidding process, not just the initial phase but as it is intended to be implemented throughout its entirety on rural health care delivery?

Mr. WILSON. We have not done that type of analysis to this point because rural areas are excluded from the program. We have not yet done rulemaking on how to expand the use of those prices by 2016 where we would do such an impact analysis.

Mr. BRALEY. Do you understand why patients in rural America have serious concerns about a shrinking market to meet their health care demands if the impact of the long-term competitive bidding process results in the shrinking or available suppliers and an unwillingness on the part of some of the remaining people who are eligible to participate to go into areas where volume will not allow them to achieve the type of margins they could have factored in when they presented their initial bid application?

Mr. WILSON. I think that what beneficiaries need is choice and quality and I think that can be sustained under this program.

Mr. BRALEY. Are you aware that in a host of other purchasing opportunities that people in rural America have substantially fewer choices in the marketplace than people in more populated areas?

Mr. WILSON. I think it is certainly true that there are challenges in rural health care.

Mr. BRALEY. Have you ever lived in rural America, Mr. Wilson?

Mr. WILSON. I have not.

Mr. BRALEY. Well, I have. I grew up in a town of 1,500, and most of my district is considered rural America, and we see lots of policymakers who come to committee hearings like this and try to tell us how they are going to fix the problems in rural America but I can tell you that for those of who deal with these problems on a daily basis, this is more than just paranoia. This is what we have seen happen on the storefronts and shops in our cities and towns. It is a problem where every time a drugstore goes out of business in a rural community it denies access to people who need durable medical equipment. Every time a provider who is furnishing DME services to those small town hospitals and health care providers, once they go out of business, we aren't as confident maybe as CMS is that the big players are going to be willing to come to our part of the country and continue to compete for our health care dollars. Do you believe that a decrease in the number of supplies in rural areas could impact accessibility and timeliness of receiving durable medical equipment?

Mr. WILSON. I am not sure that we are going to see a decrease in suppliers in rural areas. I think we have not moved forward with the authority that we have to apply the prices in rural areas, and of course, competitive bidding does not apply there.

Mr. BRALEY. Well, as Johnny Cash sang, "I hear the train a comin," and I think everybody in rural America knows that this is inevitable.

Mr. Levinson, I really was interested in a number of the comments that you made in your report. I want to focus on a few of those. You appropriately noted the challenges that we are facing in health care. We talk about this on this subcommittee. And dealing with what some people have identified as a $500 billion to $700 billion problem in this country, not just in Medicare and Medicaid but across the health care reimbursement system in waste, fraud and abuse, and you have identified enrollment, payment, compliance, oversight and response issues that need to be addressed. One of the things you talked about was that DME is one of those areas where we see problems with people getting in at the entry level and then it becomes hard to monitor them once they are set up and doing business, but I guess I am a little confused because if the purpose of having a certification requirement that a good or service is medically necessary before it can be prescribed and paid for by public or private reimbursement systems, why is it a challenge for anybody receiving Medicare payments, whether they are DME providers, pharmaceutical providers or other health care providers to be identified at the point of entry and be held to a level of accountability that protects consumers of health care in this country?

Mr. LEVINSON. Well, over time it has certainly become apparent that it has been too easy to get a provider number. Enrollment has been a fundamental flaw for many years in terms of just gaining

entry to the program. When our auditors and evaluators, for example, went to south Florida a couple of years ago and just banged on doors or tried to bang on doors because actually there were no doors to bang on, we found that about one-third of the 1,500 or 1,600 DME providers in south Florida, those who had registered and gotten a number, didn't make even the most basic standards for being able to gain entry to the program like having a physical location, like having regular hours, staffed by somebody who could actually help. So it is quite clear that it has simply been too easy to gain access, and to the extent that we can fix the enrollment issue among those five issues that you and we have identified, you really solve a lot of the consequential issues that we have to deal with when it comes to compliance, oversight and response. It doesn't necessarily deal with pricing methodologies with being able to align prices so that they better reflect market realities, and some of our pricing reports indicate that Medicare indeed pays too much and, you know, we have done some comparative work, much as with VA, which one might argue is a different kind of structure but with a federal employee health benefits program as well and with Internet pricing.

So the pricing issues are perhaps somewhat related to enrollment but I think that the enrollment issue to the extent that we can get on top as a department of the enrollment issues, that will solve a lot of the blatant fraud issues, and again, you know, fraud is a segment of a larger issues but one of the most promising aspects actually of the Affordable Care Act is the mandating of a compliance program for health care providers, and I think by having compliance built in to Medicare going forward across a wide range of industries, we will be able to do a much better job of protecting taxpayer dollars and actually giving value to beneficiaries.

Mr. BRALEY. Thank you for your time. I yield back.

Mr. PALLONE. Next is the gentleman from Maryland, Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman.

Mr. Wilson, I just want to make sure I understand the problem. I got here a little bit late but I did watch some of it on the monitor. The fee schedule that was put in place back in the late 1980s, that has continued to inflate over time and therefore bears much less connection, any kind of rational connection or reasonable connection to the actual pricing structures out there, at least with respect to some of these durable medical equipment items, correct?

Mr. WILSON. That's correct.

Mr. SARBANES. And the unreasonable relation is that it is paying a lot more in many instances and one could justify just looking at the market so the competitive bidding process is a response to that, and we talked about what some of the issues are with that process.

I had a couple questions. One was, where else has CMS done this kind of competitive bidding as a response to similar kinds of issues and what has the experience been with that? And what are the reasons you go the competitive bidding route as opposed to just working harder to come up with a fee schedule that bears a more reasonable relationship year in and year out to the underlying market and price structures that are out there?

Mr. WILSON. I think this program is pretty unique for Medicare. There has been a lab demonstration on competitive bidding. There are, I think, really not many other examples that would be even close to this type of program, and I think going to your second question, this program has a unique set of challenges in terms of setting prices and calculating or computing a new fee schedule. There is a lack of data on what items actually cost, so I think one of the reasons for competitive bidding was going to the only place to get to a true market price, which was the suppliers and bidding.

Mr. SARBANES. I guess drug pricing is another place where the data sets are pretty opaque in terms of understanding why things cost what they do.

Mr. WILSON. I am less familiar with that program. It doesn't fall within my purview. But, you know, I think it is an area where manufacturer information is one of the only areas to get pricing information.

Mr. SARBANES. When the original fee schedule was established, would you say it was easier to get hold of the kind of data that could construct a fee schedule at that time than it is now or that was just the method to be used at that point with all the flaws that it bore?

Mr. WILSON. Historically, there was a quote, unquote, reasonable charge-based payment system, essentially some discount off charges provided by suppliers. That was the only information available. Those charges were in many cases inflated or distorted but they were locked into the fee schedule for 20 years.

Mr. SARBANES. And just in terms of the details of the competitive bidding process, I don't know enough about how it is set up but are there baskets or ranges or parameters or corridors in which the competitive bids can be submitted or is this sort of anything goes in terms of being able to enter the bid process?

Mr. WILSON. We——

Mr. SARBANES. In other words, is it kind of a managed competitive bid process in that sense or——

Mr. WILSON. Well, I think it is a managed process in that we have a number of different criteria for qualifying suppliers to bid that relates to quality standards, financial standards, licensing, other things, and then we have processes to verify that bids are what we call bona fide. We try to ensure that they are not submitting a low-ball speculative bid.

Mr. SARBANES. But there is no, like, floor, for example, on what the bid can be?

Mr. WILSON. No, there is not a floor other than the ability to document that a price is rational and feasible to provide the service. There is a ceiling which is the current fee schedule.

Mr. SARBANES. OK. Thanks.

Mr. PALLONE. Thank you.

Mr. Doyle.

Mr. DOYLE. Thank you, Mr. Chairman, and I want to thank the subcommittee's courtesy for allowing someone who is not a member of the subcommittee to ask some questions.

I have the privilege of representing Pittsburgh in the Congress, and Pittsburgh was one of the nine round one test sites, and obviously I have been hearing from many of my constituents in the

Pittsburgh area that I think have very valid concerns. Mr. Chairman, I have more questions than I have time for so I would like to submit additional questions for the record to maybe get them answered. One parallels Ms. Castor's concern about a company that announced it was awarded 17 contracts, and this is a company that had publicly said back in May that if they couldn't get their debt down they were filing for bankruptcy in the spring. So we do have concerns that we are not giving contracts to companies that aren't going to be able to sustain themselves, and it is one of the real concerns we have in Pittsburgh too with these bids coming in at seemingly artificially low prices just for companies that want to sustain themselves and stay in business whether these companies are going to be able to be viable 3 years down the road at some of these prices that they are competing with.

Before I get into that, I have a specific question on glucose testing strips I want to ask you. Diabetes is a big problem in my district, and I have concerns about the availability of glucose testing strips. My understanding that mail order suppliers are required only to carry one brand and not necessarily the brand that patients use, and as you know, these strips are unique to the machines that they use just like razor blades are to certain razor handles. And I understand that DME providers are permitted to provide a monetary incentive to patients to switch monitors if they can't get the test strips to go with their monitors, but a lot of my patients in Pittsburgh, we have an elderly population. They are seniors. It is very problematic for them having to switch monitors, and what I want to know is, how does CMS know that the suppliers are going to be able to furnish the volume of specific products that will be demanded through the competitive bidding program? For example, does CMS know, for instance, that suppliers who contract for Pittsburgh will be stocking and selling strips that work with Lifescan's One Touch Ultra meters. Thirty-five percent of my district uses that monitor. And if a supplier chooses not to offer strips that work with Life Scan's One Touch Ultra or any other brand strips that a beneficiary uses, what options are available to that beneficiary to obtain replacement stripes?

Mr. WILSON. If I could just go back and reference a few of the statements that you made, sir. We don't specifically say you are only required to provide one brand of test strips. In fact, when I look at the bid information that came in, and we collect information on all the models, products and services that will be provided under the program and will update it quarterly, I see a full range of products in the particular ones that I have looked at.

Mr. DOYLE. Are you saying you don't require them only to carry one brand, you require them to carry multiple brands?

Mr. WILSON. We require them to submit a bid on brands, on the brands that they intend to provide.

Mr. DOYLE. Are they required to carry more than one brand?

Mr. WILSON. We don't say that, no, sir.

Mr. DOYLE. So theoretically, they could carry one brand and be in compliance with the bid?

Mr. WILSON. Theoretically, but that is in fact not what happens because suppliers come in, they want business. They know they

need to provide the items that beneficiaries want if they are going to be viable.

The other thing that I would say is, I am not aware of any ability to offer a monetary incentive. I am not the OIG. That would possibly implicate anti-kickback, although I won't make that judgment. That is for others.

Mr. DOYLE. So tell me, what happens to—let us just say for instance if I have seniors in my district that have a monitor that needs a specific test strip and it's not available, what are their options?

Mr. WILSON. Their options are several. If it is not available, and we certainly hope and expect that it will be, they could talk to their doctor about physician authorization requirement, the law which allows them to certainly pursue something that is medically necessary from a supplier. We have not bid test strips in retail stores. A beneficiary could obviously go to any retail store in Pittsburgh and——

Mr. DOYLE. Yes, but doesn't that sort of defeat the purpose of the competitive bidding program if they end up going to the pharmacies? I am going to submit more questions. Boy, 5 minutes goes fast. Because I want to ask you another question before my time is up.

You know, a lot of people on the surface don't have a problem with this idea of competitive bidding so long as it doesn't affect quality and access, and I think that is really the concern that we have about this quality and access, and I know CMS is surveying customers regarding the level of service and quality of care changes. My question is, what happens if there is an identification of a change in quality or service? Is there some percentage or formula that would trigger some event or reaction by CMS and doesn't it concern you that your analysis of round one won't be complete before you expand this program to an additional 91 areas in round two? How do we measure quality of care and access and at what point is that is not happening? Is there a definitive formula? Is this subjective? You know, tell me how that is going to work.

Mr. WILSON. Well, first of all, we are concerned about any concern, whether it a systemic concern or individual beneficiary concern and we will be collecting information and have the infrastructure in place to evaluate those and deal with them.

The other thing I would say is that we are evaluating the program phase by phase as we move forward. I mentioned that we are going to be collecting claims data, active claims surveillance as the program moves forward so, you know, beginning very soon after January when the claims start coming in, we will be able to see what is going on. We will see who the beneficiaries are, whether they are going to the doctor's office, the emergency room, other types of problems.

Mr. DOYLE. And if you are seeing these problems in quality of service and access, how will you respond to that? How do you change what you are doing?

Mr. WILSON. Well, we will have to examine the particular situation and see what the problem is. We will have to identify whether it is a particular problem with suppliers not meeting quality stand-

ards, whether it is particular suppliers having other types of difficulty. But we will certainly collect that information and examine it.

Mr. DOYLE. Mr. Chairman, you have been very generous with your time and I appreciate it, and I will submit the rest of my questions for the record.

Mr. PALLONE. Absolutely. And let me——

Mr. DOYLE. And so has the ranking member.

Mr. PALLONE. Oh, yes, and the ranking member.

Let me mention, we had an unusual number of members actually who said they are going to submit written questions, which is fine. We try to get them to you within 10 days. The clerk will try to get them to you within 10 days and then of course we would like you to get back to us as quickly as possible. I don't think I have ever had a hearing where there were more members who said they were going to submit written questions. So thank you very much and I appreciate your input on such an important subject. Thank you. And I will ask the second panel to come forward.

Let me welcome the second panel and introduce each of you again. From my left is Ms. Karen Lerner, who is a Registered Nurse with Wound Care, Support Surface, and she is also a Rehab Specialist at Allcare Medical. Where is Allcare Medical located?

Ms. LERNER. Sayreville, New Jersey.

Mr. PALLONE. Sayreville, New Jersey. You are my witness. I mentioned it earlier, and I was hoping that I was going to mention that again. Thank you.

And then Mr. Alfred Chiplin, Jr., who is Managing Attorney for the Center for Medicare Advocacy. And Ms. Nancy Schlichting, who is President and CEO of Henry Ford Health System. I am going to ask where that is also.

Ms. SCHLICHTING. In Detroit.

Mr. PALLONE. In Detroit. And Dr. William Scanlon, who is a Health Policy Consultant. Where are you from, Dr. Scanlon?

Mr. SCANLON. Washington.

Mr. PALLONE. From Washington. All right.

As I think I mentioned before, we try to keep everything to 5-minute opening statements. I think the panelists have been pretty good about sticking to the 5 minutes. It is the members that have not, so I am not going to say anything further, but if you want to submit additional written comments as a follow-up, you may well.

And I will start with Ms. Lerner.

STATEMENTS OF KAREN LERNER, REGISTERED NURSE, WOUND CARE, SUPPORT SURFACE AND REHAB SPECIALIST, ALLCARE MEDICAL; ALFRED CHIPLIN, JR., MANAGING ATTORNEY, CENTER FOR MEDICAL ADVOCACY; NANCY SCHLICHTING, PRESIDENT AND CEO, HENRY FOOD HEALTH SYSTEM; AND WILLIAM SCANLON, HEALTH POLICY CONSULTANT

STATEMENT OF KAREN LERNER

Ms. LERNER. Mr. Chairman and members of the subcommittee, my name is Karen Lerner and I am a Registered Nurse and Wound Care Support Surface and Rehab Specialist for Allcare Medical in

Sayreville, New Jersey. Allcare has been in business since 1963. We have 200 employees and serve about 25,000 patients per year. Allcare Medical is a member of the Jersey Association of Medical Equipment Services and the American Association for Home Care.

I am here today representing the home care community. My goal is to explain why this competitive bidding program as designed by CMS will not achieve its desired outcomes and will in fact reduce access to care for Medicare beneficiaries, lower the quality of that care, increase cost and kill jobs.

We agree with the 255 members of the House of Representatives who believe this program should be scrapped. Numerous consumer and patient advocacy organizations also believe the bidding program should be eliminated. The fundamental flaw in the design of this bidding program for durable medical equipment is that it treats home medical equipment and services like a simple commodity. We are not equipment deliverers; we are service provider.

In fact, effective home-based care for our Nation's seniors and people with disabilities is an integral part of the continuing care that helps move patients from hospital to the home. It helps to keep people out of nursing homes and the emergency room and it reduces hospital admissions. Many frail, elderly and disabled Medicare beneficiaries require multiple items of medical equipment. Consider the chaos that will occur when a caregiver must call five or six different companies to coordinate the medical equipment needs of a patient who requires a hospital bed, support surface, oxygen, enteral feedings and a walker. I have seen many, many patients like this. As a Nurse and an Assistive Technology Professional who helps patients get fitted for the right type of wheelchair, I am in contact with patients every day, and it scares me to think of what will happen to these patients if this bidding program becomes reality.

The current marketplace without competitive bidding requires home care providers to compete for patients on the basis of service and choice to furnish the home medical equipment that makes the most clinical sense for the beneficiary. We are currently reimbursed under fee schedule in Medicare CMS and Congress have cut repeatedly and disproportionately over the past decade so the contention that the DMEPOS fee schedule is outdated and is based on pricing from 25 years ago is incorrect. The home medical equipment sector has already seen reimbursements cut nearly 50 percent to the Medicare fee schedule over the past decade. Despite all the quality assuring and measuring tools that CMS has previously touted, patients and even most physicians will not know if they are getting clinically appropriate equipment and services until negative outcomes appear.

With respect to all of the promised savings and advantages of the competitive bidding program, I maintain that what sounds too good to be true is too good to be true. This ill-conceived program will single-handedly destroy the home medical service sector, harm the patients we serve and ultimately increase Medicare costs.

Now let me describe the problems we have seen in the re-bid process. A provider in Ohio was offered a contract for a respiratory device but they didn't have a respiratory therapist on staff contrary to the bidding rules and contrary to Ohio law. One of the largest

home care companies announced in July 2010 that it was offered 17 contracts in the first bid despite the fact that in June 2010 it had $513 million in long-term debt, was considering restructuring or filing for bankruptcy and expects to lose up to $900,000 in the bidding areas in the first quarter of 2011.

Let me speak to the issue of transparency. One hundred and thirty-six members of Congress who sent a letter to CMS recently believe that CMS has not shared enough information about the program. Transparency is intended to protect the public. The lack of transparency makes deficiencies in the program and makes it impossible to evaluate fully the way CMS reached it various decisions at every stage of the process. From an Administration that touts its openness and transparency, we have seen none with this program.

On the question of fraud prevention, first let me say that home medical equipment providers have no tolerance for fraud but arbitrarily limiting the number of legitimate providers in the marketplace will do nothing to stop those whose only intent is to defraud the Medicare program. The HME community should not be penalized when CMS grants Medicare billing credentials to an empty closet. The government is simply not doing an adequate job of site inspections before awarding suppliers. As a Nurse and with direct experience in the home care medical field, I believe this program will increase costs rather than save money. Patients I see will suffer through limited access to clinically appropriate equipment and services. It will reduce the quality of equipment beneficiaries receive and many will end up in the hospital. This program will not be fixed as it is designed. Therefore, JAMES, AAHomecare and a large number of patient organizations believe that Congress must immediately stop the implementation of this bidding program and work with the HME community to ensure accurate pricing while at the same time ensuring access to quality care for Medicare beneficiaries.

Thank you again for the opportunity to provide testimony.

[The prepared statement of Ms. Lerner follows:]

Testimony of Karen A. Lerner, RN, MSN, ATP, CWS

Registered Nurse, Wound Care, Support Surface & Rehab Specialist for Allcare Medical, Sayreville, NJ

Before the Subcommittee on Health

House Committee on Energy and Commerce

On

Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access

September 15, 2010

I would like to thank Chairman Pallone, Ranking Member Shimkus, and members of the Energy and Commerce Subcommittee on Health for the opportunity to provide testimony for the hearing on "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access."

My name is Karen Lerner and I am a Registered Nurse, Wound Care, Support Surface & Rehab Specialist for Allcare Medical in Sayreville, New Jersey. Allcare Medical is a full service HME company specializing in complex rehab equipment, clinical respiratory, wound care and support surfaces, as well as custom orthotics and prosthetics. Allcare Medical employs over 200 associates with three locations throughout New Jersey and one location in Pennsylvania and provides equipment and services to over 25,000 patients annually.

Allcare Medical is a proud member of the Jersey Association of Medical Equipment Services (JAMES) and the American Association for Homecare (AAHomecare). JAMES represents providers of home medical equipment in New Jersey. It is the goal of JAMES to keep its members informed of industry changes and related information necessary to maintain quality of care in providing home medical equipment, supplies and services to the patients.

AAHomecare is the national trade association for health care providers, equipment manufacturers, and other organizations in the homecare community. AAHomecare members serve the medical needs of Americans who require oxygen equipment and therapy, mobility assistive technologies, medical supplies, inhalation drug therapy, home infusion, and other home medical products, services, and supplies in the home.

I've been a Registered Nurse (RN) for the last 28 years, 14 years of which I worked with home medical equipment (HME). Unfortunately, I and many other providers have seen the significant flaws in the Centers for Medicare & Medicaid Services' (CMS) design of the bid program that will cause Medicare's most vulnerable beneficiaries to experience a range of unintended consequences that affect choice, access, and quality in the DMEPOS benefit. I am concerned that the HME competitive bidding program will result in beneficiaries experiencing more medical complications, increased use of emergency room care, and delays in hospital discharges

(increasing hospitals' costs). The program will compromise beneficiaries' ability to live independently in the most cost effective setting – their homes.

I'm here today to provide information to the Committee about my concerns with the competitive bidding program from my clinical experience in New Jersey, as well as from a national perspective.

Clinical Perspective of Competitive Bidding

As both an Assistive Technology Professional (ATP) and a nurse, I am in contact with patients, the end users of HME, every day and it scares me to think of what will happen to these patients if Competitive Bidding becomes reality. Competition in the marketplace forces me and other HME company employees to provide customers with service and choice, to offer equipment that does not make the most profit but makes the most sense, clinically. Competitive bidding is competition in name only. In fact, it is anti-competitive.

There are over 200 Medicare-approved Group 2 support surfaces. Some cost the provider under $400, some cost the provider over $10,000, but the Medicare reimbursement is the same, regardless of the provider's cost.

Currently, HME companies compete for the support surface business and can offer a variety of products to meet customer needs. Under competitive bidding, providers would have to furnish the least expensive product or lose money on every group 2 support surface order. If every patient who needed a group 2 was placed on the least expensive support surface, most of those patients' pressure ulcers would worsen and they would end up in the emergency department or be admitted to hospitals for surgical debridement. I see patients on inferior support surfaces and improper low-end wheelchair cushions get re-admitted to hospitals for pressure ulcers every day. Ordering clinicians stop using the HME company and call a more reliable HME company for the same equipment. Competitive bidding will stop the ordering clinician and patient from making this choice. In these cases, which I believe will be increasingly common under competitive bidding, costs will not only shift from Part B to Part A of the Medicare program, but patient care will be compromised and negative outcomes will become commonplace.

Recently, a New Jersey Rehab Institute ordered a low air loss (LAL) group 2 support surface for a discharged patient with multiple pressure ulcers. We delivered a LAL but the patient's home lost electricity that night and the patient sunk down to the metal bed frame and refused to ever again sleep in a low air loss, yet he needed it for his pressure ulcers to heal. Allcare Medical stocks LAL with solenoid valves that will retain air pressure when electricity fails. These are very expensive units and our reimbursement is actually below our cost, but because we were also supplying the patient with the bed and enteral feeding we were able to provide him with the special LAL. Competitive bidding would preclude providers from providing the best equipment for the patient due to dramatic cuts in reimbursement and the possibility that the company did not win any other bid categories (i.e. beds) to supplement the loss.

Since beds are separately bid from support surfaces, one company may win the bid for hospital beds and another for support surfaces, yet the support surfaces have to be secured to beds and work with the side rails and other bed accessories. Sometimes mattresses have to be removed before the Group 2 support surface can be placed. Patients who require group 2 support surfaces

have pressure ulcers that have worsened over time. They are frequently bedridden but need to be out of bed to take delivery of the support surface. If the bed arrives with no mattress, in anticipation of the support surface, the patient cannot be put to bed. If the support surface arrives before the bed, the support surface cannot be set up and the patient cannot be put to bed. I wonder if the patient can figure out which company to call when the bed is malfunctioning. If the bed-providing practice needs to exchange its bed, they very often will not know how to remove and replace the group 2 support surface, as many require specific calibrations to work effectively.

The Medicare program requires that any HME providing complex rehab employ specialized staff, Assistive Technology Professionals (ATP), to analyze the needs of individuals with disabilities and assist in the selection of the appropriate equipment. The beneficiaries of complex rehab are those with conditions different from the traditional elderly Medicare population. This population group, who tends to qualify for Medicare based on their disability and not their age, consists of individuals with diagnoses of cerebral palsy, muscular dystrophy, amyotrophic lateral sclerosis (Lou Gehrig's disease), spinal cord injury, and spina bifida. This population nearly always requires more traditional equipment as well, such as beds, support surfaces, oxygen, and enteral feedings. Imagine the hospital or sub-acute discharge planner who has to call 5 or 6 companies to coordinate the HME needed for these individuals and the families of these patients who receive bills and EOBs from 5 and 6 companies every month. HME providers provide health care, ours is not a delivery service. Patients know this and they rely on that service provider, not 5 of 6 delivery-service companies.

Respiratory therapists (RTs) evaluate patients to determine the best respiratory equipment that will meet the needs of specific patients. Are they highly ambulatory? Do they require high liter flows? Do they use a PAP device at night with oxygen entrained and O2 during the day? Can they tolerate a conserving device? RTs will perform pulse oximetry to make sure that the patient does not desaturate if they are using a conserving device or a pulsed dosed system (conserving devices on portable cylinders, portable oxygen concentrator or liquid oxygen system). HME companies are not reimbursed for any of these services. Yet, these are the services patients receive in a competitive environment. These vital services would not likely continue under the competitive bidding scenario.

Credit has also tightened significantly since the collapse of the credit markets in 2008 and businesses are finding it much harder to secure credit. As a result of dramatically reduced reimbursements and profits, many winning bidders will not be able to secure ample credit to support the capital requirements for this new found business. This scenario is very realistic as we are personally experiencing tightening credit even at the current rates of reimbursement. What will happen when many companies cannot obtain the financing and buy the equipment and make the necessary investments to provide to their new captured audience (the patient)?

I am also concerned with the negative impact competitive bidding will have on patient care during a national disaster or weather emergency. Between 4pm and 9pm on August 30, 2010, Monmouth County experienced an extensive power outage affecting more than 70,000 residences. Allcare responded to dozens of calls from oxygen patients (or their caregivers) asking for additional back-up tanks since their electric oxygen concentrators were temporarily not functional. Allcare was able to deliver tanks to dozens of patients within just a few hours of each call. Not one patient ran out of oxygen from their original back-up tanks. What if there

were more widespread outages caused by a natural disaster or even an act of terrorism? How would a limited number of providers be equipped to effectively provide backup tanks needed to potentially thousands of their patients in relatively a few hours? How many hospital admissions would result if these few providers failed to deliver back up tanks timely?

I maintain that what sounds too good to be true, is too good to be true and this ill-conceived anti-competitive program called competitive bidding will single-handedly destroy the home medical services sector which will preclude patients from living safely and independently at home, the best, safest, most preferred and cost effective environment for the patient.

In most cases the prescribers of HME are not familiar with all the HME technology that is available. The ordering clinicians, through trial and error, have come to rely and trust the HME companies they use, to provide their patients with the best equipment for optimal outcomes in the needed time frame. What recourse do the ordering clinicians and patients have if the bid winner cannot offer the products and services they require?

Homecare is the answer to our nation's health care crisis and this bidding experiment is an economically-crippling initiative that will annihilate the slowest growing, most cost-effective, preferred source of care for our society.

I would now like to provide the Committee with my concerns from a national perspective.

Home Medical Equipment is Cost-effective Care for an Expanding Older Population

HME is an efficient and cost-effective way to allow patients to receive care they need at home. Approximately eight million Americans require some type of medical care in the home. Today, virtually any medical procedure short of surgery can be performed in a patient's home. Homecare represents a small but cost-effective portion of more than $2.3 trillion national health expenditures (NHE) in the United States

The older population in the US is expanding. There were 39.6 million older Americans (age 65 or older) in 2009, representing 12.9 percent of the population in the U.S. There were 4.6 million elderly Americans aged 85 and older. By 2030, there will be about 72.1 million people over 65, more than twice their number in 2000. The population aged 85 and older is the fastest-growing segment of the older population, with a projected increase from 5.8 million in 2010 to 8.7 million in 2030. The need for HME and HME providers will continue to grow to take care of the ever-increasing number of older Americans.

As more people receive good equipment and services at home, we will spend less on longer hospital says, emergency room visits, and nursing home admissions. Home medical equipment is an important part of the solution to the nation's healthcare funding crisis. Home medical equipment represents less than two percent of Medicare spending. So while this bidding program may reduce reimbursement rates for home medical equipment, ultimately, it will increase Medicare and Medicaid spending for hospitals, physicians, nursing homes, and emergency treatments.

History of the HME Competitive Bidding Program

Round One Bid Process

The Medicare Modernization Act of 2003 (MMA) requires Medicare to replace the current HME payment methodology for certain items with a selective contracting process. Any provider not awarded a contract will be prohibited from providing bidded Medicare items for the length of the contract, typically a three-year period. The program was slated to go into effect in 10 metropolitan statistical areas (MSAs) across the country, expanding to an additional 70 MSAs in subsequent years. CMS has the authority to conduct additional rounds of bidding in other areas or apply the bid rates from one MSA to an area where bidding did not take place.

The Patient Protection and Affordable Care Act (ACA) further accelerated this implementation by adding an additional 21 MSAs to Round Two and mandating that competitively bid pricing be in place in all MSAs by 2016. This authority is of particular concern because CMS can apply the bid rates from the large MSAs in Round One to smaller urban areas or rural areas where the costs of providing HME items and services to patients may vary significantly. CMS began implementation of the program in 2007.

During the initial Round One bidding process, a significant number of providers who were awarded contracts could not deliver services commensurate with their bids, creating scenarios where beneficiary access to quality home medical equipment and services was reduced. These problems included awarding contracts to inexperienced or non-local providers, unlicensed providers, providers who did not have financial resources to ramp up to deliver services to a larger number of patients, and some "winners" attempting to sell their contracts but failed due to responsible providers not being able to provide the product and service at these bid amounts.

On December 8, 2009, the GAO released a report entitled, 'CMS Working to Address Problems from Round One of the HME Competitive Bidding Program'. The GAO report said CMS provided unclear and inconsistent information, particularly regarding bidding requirements and financial information. Some bids by equipment providers were incorrectly disqualified. The report further details the lack of notification to providers about the post-bid review process. The GAO report also notes that its report did not identify "concerns with the overall structure and design" of the bidding program because "such an analysis was beyond the scope" of the report.

The problems associated with this process ultimately led Congress to include a provision in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) delaying the program in order for CMS to address these issues. To pay for this delay, the HME sector agreed to a 9.5 percent cut in Medicare reimbursement. Unfortunately, CMS ignored the underlying purpose for delaying Round One, which was to give CMS and providers the opportunity to identify and correct the implementation flaws that had plagued the "first" Round One. In passing MIPPA, it was Congress' belief that § 154(b) would effectively delay a new Round One for a period of at least 18 months, which would be adequate to address the problems that had been identified. When he introduced H.R. 6252 (later incorporated into MIPPA as Sec. 154(b)) to delay Round One, Representative Pete Stark, the sponsor of the legislation in the House, stated:

> "Without Congressional intervention, the flawed program begins on July 1, 2008. The bill we're introducing today delays implementation of the competitive bidding program

> for 18 months to provide the Centers on Medicare and Medicaid Services (CMS) with the time to create an improved program based on standards laid out in this legislation."

Similarly, Senator Charles Grassley introduced legislation with a sense of the Senate provision to delay the competitive bidding program for 18 months. The Grassley bill stated:

> "Implementation of competitive bidding for durable medical equipment, prosthetics, orthotics, and supplies should be delayed by 18 months to address concerns and ensure beneficiaries continued access to quality medical equipment and supplies. "

[Statements on Introduced Bills and Joint Resolutions 154 Cong. Rec. S5525-01, S5528)]

In fact, at the time it was passed, § 154(b) was widely understood by both its supporters and opponents as intended to delay competitive bidding for at least 18 months to give CMS an opportunity to make changes in the program. In a statement supporting the President's veto of MIPPA, Representative Joe Barton stated:

> "The bill before us, if the veto is not sustained, would delay-and I'm being charitable to use that verb-the reform of competitive bidding for durable medical equipment. It would delay that for 18 months, which in all probability would kill a program that would save billions and billions of dollars if implemented."

Medicare Improvements for Patients and Providers Act of 2008-Veto Message from the President of the United States (H. DOC. NO. 110-131) 154 Cong. Rec. H6520-04, H6521).

Floor statements in the House and Senate clearly show Congress' understanding that §154(b) would delay Round One for at least 18 months. This understanding of §154(b) was so widespread in the days leading up to its enactment, that we were surprised when CMS published the IFR, completely avoiding the requirement to solicit public comments and create an administrative record for the rule. The preamble to the IFR states that formal rulemaking is unnecessary because the statutory requirements of § 154(b) are self-implementing. Even assuming this is correct (which we dispute as we noted above), CMS nonetheless ignored the factual context, which prompted Congress to intervene by delaying Round One.

Congress did not delay Round One for the sake of delay; Congress believed it was giving CMS more time to make meaningful changes to the program. Based on the events precipitating the delay of Round One, it was the belief that at the very least Congress expected CMS to solicit public comments with the goal of improving future rounds of bidding. Instead, CMS has moved forward in a vacuum, incorporating little feedback from stakeholders on how to avoid the mistakes of Round One.

Round One Re-bid Process

On January 16, 2009, CMS released the interim final rule on the competitive bidding program to implement changes to the program. Unfortunately, CMS failed to make any substantive changes to the competitive bidding process. The Agency made only minimal changes required under MIPPA while relying on the original, flawed final rule for the methodologies used in selecting providers and calculating payment rates. This was all done without consulting the PAOC or

allowing for public input. When the competitive bidding rule was released, I anticipated the same problems that plagued the initial roll-out of the program to re-occur.

Examples of Round One Re-bid Problems

- One provider in Texas received an enteral nutrition contract but did not submit a bid for entral nutrition.
- One provider in Ohio was offered a CPAP contract but does not have a licensed respiratory therapist on staff where it is a requirement to have licensed respiratory therapists to provide CPAP devices.

On July 1, 2010, CMS announced the Round 1 re-bid single payment amounts and touted 32 percent in savings from the competitive bidding process. I am very concerned that these bid rates are unsustainable and will negatively impact patients' access to the home medical equipment that they need.

If the fundamental mechanics, which were not changed, led to the failure at a reimbursement rate reduction at 26 percent before 2008 allowable, why should we expect the program to work with an average 41 percent reimbursement rate reduction? CMS has not provided any substantive information to the public to analyze the Round 1 bid rates. While proclaiming the low bid rates, CMS has failed to provide basic information about the bid process and the HME providers that will be offered a contract.

Although CMS has released little information about the Round One Re-bid process, I was concerned by a statement made by a CMS official about some of the bid winners financial stability. During a press call on July 2, 2010, he stated –

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

Round Two Bid Process

CMS is scheduled to begin the Round Two bid process in 2011. Round Two bidding will occur in 91 MSAs and will affect most of New Jersey. I am concerned with the effects this massive expansion of competitive bidding will have on 1.3 million Medicare patients in New Jersey, as well as patients across the county. The following are specific examples of how competitive bidding will affect New Jersey:

- The recent expansion of competitive bidding in the ACA legislation will include 17 out of 21 New Jersey counties in Round Two bidding, which equates to 80 percent of the state. Chairman Pallone's 6th district, which has 86,000 Medicare patients, will be

entirely affected by the bidding program. In less than six months, New Jersey providers will be required to register as bidders, and begin the actual bidding process.

- The recent passage of ACA, a new eligibility group has been added to many state Medicaid programs. In New Jersey it is expected that the Medicaid program will be responsible for ensuring an additional 300,000 - 900,000 lives. While competitive bidding is a program that will immediately impact the Medicare program, caution should be exercised when the reduction of providers is considered. If providers are reduced by approximately 90 percent, this will not only affect the Medicare population, but the Medicaid population as well, creating additional burdens to CMS.
- There are potential job losses of 14,831 in the three overlapping MSAs that will affect NJ, and the potential closure of 1,483 companies, as referenced in "DME Competitive Bidding Will Cost More Than 100,000 Jobs" informational brochure, 2010.
- Credit markets for small businesses remain difficult to access in New Jersey. With the competitive bidding program poised to disallow the participation of an alarming amount of current Medicare providers, bid winners will need to have timely access to lines of credit and small business loans to have the ability to service the increased volume of Medicare beneficiaries. In the current economic climate, it appears these options are not readily available.

Consequences of Bidding

The Medicare bidding program is a poorly conceived and fundamentally flawed program that is now exhibiting many of the serious breakdowns that are predictable based on its failure to recognize and account for the true nature of the way home medical equipment is provided to Medicare beneficiaries. These breakdowns have been evident since the start of the Round One bidding process in early 2007, throughout the bid evaluation process, and right through the recent awarding of contracts. Design and operational problems in the bidding and contracting phase will seriously compromise beneficiary access and quality of care.

The current bidding program will drive thousands of qualified HME providers out of the Medicare marketplace. One of the consequences will be limitations on services available to millions of seniors and people with disabilities.

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

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

The changes that will result from the bidding program will affect more than three million beneficiaries who reside in Round One areas. CMS has indicated that if Round Two is

implemented, approximately 50 percent of all Medicare beneficiaries requiring home medical equipment could be affected. The bidding program could also quickly affect all Medicare beneficiaries in the U.S. as early as January 1, 2015, when CMS will have the authority to apply bid pricing in non-bidding areas. The ability of CMS to apply bid pricing to non-bidding areas, especially rural areas with hard-to-reach patients, is clearly not market-based.

Impact on Beneficiary Quality of Care

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

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

Additionally, CMS will have likely awarded contracts to providers who currently have no physical presence in bidding areas. These providers have the following options. They can: (1) quickly form subcontracting arrangements with local providers, or (2) attempt to open a new location(s) to service beneficiaries residing within a bidding area. In either case, providers will have to make these changes in the next four months because the program starts in January 2011.

More than 20 million Americans currently live with diabetes, a serious and chronic disease. One in four Medicare patients suffers from diabetes and these beneficiaries account for 40 percent of Medicare spending. It is likely that a large number of beneficiaries with diabetes will need to switch providers. These new providers may not furnish the testing supplies they currently have. Alternatively, these beneficiaries can go to a local retail outlet when Medicare reimbursement is much higher. Given these statistics, it is imperative that we work to help patients more effectively manage their chronic disease. Reducing the likelihood that diabetes patients will be compliant in managing their disease should not be the byproduct of bidding.

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

There is also the real issue of providers being able to ramp up operations to meet significant new demand for medical equipment and services subject to bidding. While CMS has stated it has selected enough providers to service an entire bidding area for each product category, contract providers are going to have to be prepared for a significant increase in demand for these items and services. Based on the information provided by CMS that identifies the number of contracts that were offered in each product category and each bidding area, contract providers could see an

increase of 200-300 percent in the number of patients they are required to serve. Providers may be overwhelmed by the huge increase in volume, which their systems and infrastructure did not anticipate or may not be able to handle. This is especially true for providers who have never operated in bidding marketplaces prior to the implementation of this program. Contract providers that cannot meet demand are unlikely to provide the level of service that patients are accustomed.

These changes will also impact manufacturers who provide providers with lines of credit, which allow them, in turn, to purchase home medical equipment. These manufacturers will experience significant chaos in the credit market. These challenges will only be magnified by the annual tax on medical device manufacturers that was mandated in ACA. Good providers who lost bids will become instant bankruptcy risks for manufacturer creditors because they have no way to anticipate the impact of bidding on providers and their ability to meet payment obligations.

It will also be difficult for manufacturers to provide winning providers with the credit they are seeking given the significant payment cuts. Credit from financial institutions for winning providers who need to increase their operating capacity to meet increased demand also may not be readily available as the financial markets have recently made lending much more difficult. As a result, it will be the beneficiary who may not be able to receive the same quality of items and services that were previously provided due to credit pressures.

Impact on Beneficiary Access to Care

In the initial Round One, some providers were awarded contracts for certain product categories, which they had never before provided. Because of the lack of transparency, we do not yet know if this occurred in the re-bid process. CMS has never outlined how it evaluated a provider's self-reported plans to provide these new services. I also question how these providers could submit accurate bids for such services and items while also incorporating an unknown demand factor and operation costs into their bid calculation.

Consider the range of beneficiaries that will be impacted by bidding effective January 1, 2011:

- More than 220,000 Medicare beneficiaries who currently rely on home oxygen therapy may experience a disruption of their service if their provider does not elect to "grandfather" existing patients, and tens of thousands of new patients prescribed the therapy will have severely limited access from January 1, 2011 forward.
- 143,000 beneficiaries currently receiving home-delivered diabetic supplies may be forced to switch providers by January 1 since there is no "grandfathering" provision. Small "winners" will be overwhelmed by the rush of patients to switch providers by CMS' deadline.
- 10,000 beneficiaries currently receiving home enteral nutrition therapy may be forced to switch providers by January 1 since there is no "grandfathering" provision.

- 16,000 beneficiaries currently being treated at home for obstructive sleep apnea (OSA) may have to switch providers as they assume ownership of their equipment under the Deficit Reduction Act (DRA).
- 25,000 elderly beneficiaries currently relying on hospital beds to remain at home may have to switch if their providers do not "grandfather" due to pricing in one or more markets.

Beneficiaries also are likely to face the prospect of coordinating care with multiple providers in bidding areas. Prior to bidding, a beneficiary's home medical equipment needs could be served by one provider. Now, providers can only serve beneficiaries for items and services subject to bidding for which they have received a contract. If a beneficiary needs a hospital bed, a walker and oxygen therapy, the beneficiary may require care from three separate providers due to the mechanics of the bidding program.

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

Home Medical Equipment Provider Impact

I believe that the Medicare bidding program will radically change the HME marketplace if implemented in its current form. CMS will selectively contract with only approximately 360 unique provider companies in the first 9 metropolitan areas under the fee-for-service program. CMS' own statistics have shown that approximately 4,500 unique companies reside in these 9 bidding areas. This would indicate that CMS intends to contract with approximately 8 percent of existing home medical equipment companies. Even if we only account for the unique companies that took part in the program—1,011 companies—CMS is still threatening the financial viability of 64 percent of the otherwise qualified and accredited providers in the current homecare marketplace. Arbitrarily limiting the number of homecare companies that the market will support should be viewed as selective contracting, not competitive bidding.

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

Savings Are Questionable

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

Essentially, small providers bid unreasonably low to have an opportunity to "stay in the game" since the alternative is to go out of business. Because so many small providers bid so low, these bidders came close to meeting the capacity projections; preventing many of the larger firms' bids from being considered. I believe the extraordinarily low bid rates will be unsustainable over a three-year contracting period.

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

I anticipate that beneficiaries in the bid areas will receive lesser quality items and reduced services. Also problematic will be beneficiary disruption and confusion that will lead to additional program costs in the form of longer hospital stays, more frequent physician visits and care sought in emergency rooms. The length of hospital stays will increase while case managers/discharge planners are forced to navigate the confusing process of locating "winning bidders" (possibly several for a single patient). This will delay discharge and increase costs for Medicare part A. Also, discharge planners are used to dealing with local HME providers and may be forced to use providers that they are unfamiliar with, as well as providers who are unfamiliar with the normal discharge processes of these facilities. This is also likely to cause confusion and ultimately delay discharge. None of these factors has ever been identified by CMS in its presentation of savings that can be achieved through bidding.

Flawed Structure of Bidding System

The problem with the competitive bidding program, as CMS has implemented it, is that the bid scoring and price formulation procedures are inconsistent with the bidding behavior that CMS wants to encourage. 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.

This concept is taken from an article in the Southern Economic Journal, 2008 by professors Brett Katzman from Kennesaw State University and Kerry Anne McGeary from Drexel University.[1] Professor Katzman also released more recent information opposing competitive bidding stating that the net result of the winner's curse is that many of the reimbursement prices will be lower than the needed costs for providing those services and equipment. The winner's curse is where companies that must forecast future costs of [providing equipment and service] when formulating bids are those firms that are likely to make the lowest forecasts.[2]

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[1] Katzman,B, McGeary, K.A. Southern Economic Journal 2008, 74(3), 839-856, p.855.

[2] Dr. Katzman's research focuses on auction and competitive bidding and has been published in highly ranked peer-reviewed economics journals. His work on Medicare competitive bidding won the prestigious Dr. Katzman's research focuses on auction and competitive bidding and has been published in highly ranked peer-reviewed economics journals. His work on Medicare competitive bidding won the prestigious Georgescu-Roegen Award for best paper in the Southern Economic Journal in 2008. Dr. Katzman has served as an expert witness on competitive bidding in Federal Court and as a bidding consultant to numerous private firms.

From another economist from the Robert Morris University (RMU), the introduction of this kind of program is generally justified by a perceived market failure. Professor Brian O'Roark with RMU states that CMS has not demonstrated any major problems with the current market state. He continues "while this program appeared to encourage competition through bidding, on the supply side the number of sellers of HME were reduced. Since competition is characterized by many sellers, the laudable objective of reducing health care costs through competition seemed to be compromised." [3]

Not an Anti-fraud Tool

Some claim that the competitive bidding program may serve as an anti-fraud tool. This notion is misguided. Fraudulent providers who are out to scam the system are not concerned with the level of payment rates. They are typically in collusion with other providers (physicians and/or beneficiaries) to bill for services that are never provided. Regardless of whether HME payments are at current levels or the unsustainably low competitive bidding rates, they can continue to perpetrate fraud because they are not concerned with the costs of legitimately providing quality items and services to beneficiaries. They can afford to bid low enough to receive a contract since they are unconcerned with the costs of doing business. They can continue to provide kickbacks to physicians who order services for beneficiaries who do not require medical equipment and never receive the equipment that is ordered.

Arbitrarily limiting the number of legitimate providers in the marketplace does nothing to keep those whose only intent is to defraud the Medicare program out of the system. CMS has already taken numerous strides to reduce the potential for fraud in the HME benefit. These include requiring mandatory accreditation, mandatory surety bonds, and a recent expansion of the supplier standards that will become effective in a few weeks. This is in addition to the numerous anti-fraud and abuse provisions enacted in the ACA that are just now starting to go into effect

AAHomecare has long advocated for additional anti-fraud provisions that could reduce the number of fraudulent providers while avoiding overly burdensome policies that only hurt the legitimate providers. Unfortunately, the competitive bidding program is just another flawed tool that hurts the providers who seek only to provide quality items and services to Medicare beneficiaries in their homes.

Lack of Government Transparency

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

[3] O'Roark, B. Robert Morris University. The Impact of Competitive Bidding on the Market for DME –A One Year Update, August 2009. p. , p. 2.

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

How did CMS evaluate the financial stability of providers? How did CMS review a provider's self-reporting capacity to meet the market's need? Did CMS properly calculate the single payment amount? What criteria did CMS use to evaluate bids and determine whether a bid was a "bone fide" one? What process did CMS use to re-evaluate the bidding packages of providers who believe they were inappropriately disqualified from the program? These and other questions still remain unanswered and threaten the integrity of the bidding program. From an administration that touts its openness and transparency, we have seen none of this related to this program.

Conclusion

The fundamental flaws in the bid process still exist, which will jeopardize beneficiary access. Bidders are not bound to their bids; leading to speculative low-ball bids in an attempt to win a contract, and hoping other bidders will increase the bid price. There is no guarantee of volume of need equipment and services, making it impossible to submit a rational bid based on expected volume. CMS has set up a program that will eliminate 90 percent of qualified providers and create an access problem for all consumers of HME, not just Medicare beneficiaries. The program also fosters "suicide" bidding, which results in unsustainable payment rates: If a provider does not secure a contract, its chances of survival are slim. Since Medicare is the largest purchaser of HME items and services, CMS is using economic coercion to force unsustainable bids from homecare providers who are desperate to maintain cash flow in the hopes of staying in business. The program will destroy the current HME infrastructure that allows consumers ready access to quality items and services.

To address the fatal flaws in HME competitive bidding, Congress must immediately stop the implementation of this bidding program and work with the HME community to ensure accurate pricing, while at the same time ensuring access to quality care for Medicare beneficiaries.

Thank you again for the opportunity to provide testimony regarding this important issue. AAHomecare, JAMES, and I look forward to working with the Committee to protect patients' access to the equipment and care they need at home.

Mr. PALLONE. Thank you, Ms. Lerner.
Mr. Chiplin.

STATEMENT OF ALFRED CHIPLIN, JR.

Mr. CHIPLIN. Good afternoon, Mr. Chairman.

The Center for Medicare Advocacy takes a wait-and-see approach to the competitive bidding process. We acknowledge that it is a program that is extremely complex and confusing. Our beneficiary clients have been the victims of many efforts of misinformation. They have been frightened and confused about what this program means.

We continue to worry about the complexity of the program overall and the impact of that complexity on provider and supplier participation and thus access to specific services and items of DME that people might want.

We also are concerned that CMS's efforts at beneficiary education need to be more vigorous and visible. We think we need more to assure beneficiaries that where there might be fewer suppliers in this competitive bidding area that that will not jeopardize access.

Some major concerns that we have is that we do see that there is put forth a strong beneficiary education and access program and that the time of that education effort be very clear and specific as different phases of the competitive bidding process are rolled out. This is such a critical thing because over time this approach will redefine how all of DME is going to be meted out and I think that raises a very significant set of points.

We also need to have better information on the Web site for the Medicare beneficiaries, Medicare.gov. It is difficult to find information about the competitive bidding process. We also need better information points to access written materials. And additionally, we need more clarity about the specific items that fall within the initial rollouts of the program in 2011 so the beneficiaries have more clarity about that.

We also need additional information about the importance and significance of beneficiaries obtaining their DME within the competitive bidding area in which they live. There are real consequences for beneficiaries, particularly if they are traveling on vacation and something happens and they need to get an item fixed. So those are the kinds of concerns. As the rollout goes on with mail orders, we think some of the same kind of issues are raised in terms of the degree to which beneficiaries are informed.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Chiplin follows:]

Testimony before the

United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

Medicare's Competitive Bidding Program for Durable Medical Equipment:
Implications for Quality, Cost and Access

September 15, 2010
2123 Rayburn House Office Building

By

Alfred J. Chiplin, Jr. Esq.
And
Vicki Gottlich, Esq.
Senior Policy Attorneys

Mr. Chairman and ladies and gentlemen of the Committee on Energy and Commerce, Subcommittee on Health:

The Center for Medicare Advocacy is pleased to offer this brief testimony for today's hearing, "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access." Our testimony today focuses on access and beneficiary education, with respect to the Competitive Bidding program. The Center is a national, not-for-profit organization that advocates on behalf of older people and people with disabilities to ensure access to fair, comprehensive, and affordable health care. We are a beneficiary-focused advocacy group. Although headquartered in Connecticut, we work with beneficiaries and their advocates throughout the nation.

General Confusion about the DMEPOS Program and Access

A major concern of beneficiaries is that the Durable Medical Equipment Prosthetics Orthotics and Supplier Program (DMEPOS), including competitive bidding, not result in a decrease in beneficiary access to suppliers. At this point, there is confusion and conjecture about the consequences of the program, both positive and negative. Even so, our anecdotal experience is that suppliers are applying for certification and complying with the other DMEPOS requirements. We remain watchful as the program unfolds.

It is imperative that throughout the roll-out of the Competitive Bidding program beneficiaries are provided good, clear information about the rules of the program and about their rights and responsibilities. We are concerned that information about the program for beneficiaries is lacking and incomplete and is often difficult to find. The "Medicare.gov" website, for example, does not contain information about the DMEPOS competitive bidding program on its home page. A search for durable medical equipment on the site takes one to a Medicare Supplier Directory. When a zip code in a competitive bidding area (CBA) is entered (33394, Ft. Lauderdale, FL), the resulting page does not include information about the new program. The Centers for Medicare & Medicaid Services (CMS) publication, "What You Should Know if You Need Medicare-covered Equipment or Supplies," revised June 2010, does not appear among the listing of publications under the publications icon on the web site. One gets to the link by searching the website for "DME competitive bidding." Few beneficiaries will know enough about the program to engage in that kind of search to get basic information.

Since its inception, the DMEPOS program has been an enigma for the beneficiary community. Confusion reigns as providers vociferously opposed competitive bidding, including supplier certification, claiming that beneficiaries would not be able to obtain necessary supplies and services. We have heard concerns from beneficiaries in areas like Boston that are not subject to the DMEPOS competitive bidding program. They have heard from their suppliers that the new program will interfere with their ability to get access to supplies and/or repairs, even though they are not yet subject to the program.

Adding to the general confusion of beneficiaries about the DMEPOS program is Congressional action postponing the Competitive Bidding aspects of the program, followed by Congressional

action requiring that the Medicare agency engage in "Round 1" rebidding. And, just a few days ago, on August 27, 2010, the Medicare agency issued final regulations that DMEPOS suppliers and providers must meet. See 75 Fed. Reg. 52629. Undoubtedly, there will be months of controversy surrounding the implementation and application of these new regulations.

For beneficiaries, it is important that the Medicare agency, tasked with implementing the DMEPOS competitive bidding program, speak with a loud and clear voice about the rules of the program, the limits placed on supplies as to registration and certification, and advertising and solicitation of beneficiaries. In addition, it is important that the Medicare agency, CMS, provide clear information about what beneficiaries need to know when their DMEPOS items need to be repaired and replaced while they are out of the service area covered by their particular supplier or supplier network. Similarly, it is important for beneficiaries to have good information about their appeal rights when things go wrong, as well as good information about where they can turn for help. Right now, we are not seeing evidence of a vigorous campaign to educate the beneficiary community. CMS needs to step up its educational campaign to ensure that Medicare beneficiaries of all ages are aware of the changes. The agency's current round of educational events in ten (10) areas is not enough. Additionally, CMS needs to make clear to beneficiaries who are not in the competitive bidding areas how the new rules affect them.

What Is Covered and In What Geographic Areas

The Round 1 rebid will include the following categories of items and services: Oxygen Supplies and Equipment; Standard Power Wheelchairs, Scooters, and Related Accessories; Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2); Mail-Order Diabetic Supplies; Enteral Nutrient, Equipment and Supplies; Continuous Positive Airway Pressure (CPAP); Respiratory Assist Devices (RADs), and Related Supplies and Accessories; Hospital Beds and Related Accessories; Walkers and Related Accessories; Support Surfaces (Group 2 mattresses) and overlays in Miami.

It is important that the Medicare agency provide more clarity about the specific items of DMEPOS subject to the competitive bidding process, including clear information when new items are added to the list of DMEPOS subject to competitive bidding. For example, there is confusion over the types of wheelchairs that are not included in the program. Similarly, it is critical to provide clear information about the areas covered. For example, the competitive bidding area described as Miami-Ft. Lauderdale –Pompano encompasses many more communities than the three specifically identified. By defining the service area in terms of only three communities in this much larger and highly-populated area, CMS is creating a false sense for beneficiaries that they do not have to pay attention to the new program. Even one of our staff attorneys did not realize that her family members were in this service area because of the way it has been described.

Competitive bidding is to occur in the nine largest Metropolitan Statistical Areas (MSAs): Cincinnati-Middletown (OH, KY and IN); Cleveland-Elyria-Mentor (OH); Charlotte-Gastonia-Concord (NC and SC); Dallas-Fort Worth-Arlington (TX); Kansas City (MO and KS); Miami-

Fort Lauderdale-Miami Beach (FL); Orlando (FL); and Pittsburgh (PA); Riverside-San Bernardino-Ontario (CA).

It will continue to be critical to provide clear information when new Metropolitan Statistical Areas (MSAs) are added which will bring even more suppliers and providers into the DMEPOS program. Likewise, there is the need for information for beneficiaries who obtain their DMEPOS products through mail-order suppliers and suppliers with respect to DMEPOS requirements applicable to such supplies.

Mail Order Supplies, Including Diabetic Supplies

The purchase of diabetic testing supplies also raises problems. Under the DMEPOS rules, a Medicare beneficiary who is a permanent resident in a CBA may purchase diabetic testing supplies from a mail order contract supplier serving the area in which he or she is a permanent resident or from a non-contract supplier in cases when the supplies are not furnished on a mail order basis. In this case, the diabetic supplies will be reimbursed at the single payment amount for the CBA where the beneficiary maintains a permanent residence. Moreover, when the diabetic supplies are not furnished through mail order, the suppliers will be paid the fee schedule amount. Sorting this out will likely cause problems and may result in delays in receiving necessary supplies as well as payment problems.

Grandfathered Suppliers

Medicare's statutory and regulatory definition of covered DMEPOS suppliers is quite broad. This is made abundantly clear in the new final regulations mentioned above. We fear great confusion among beneficiaries and suppliers about these rules. In many instances, beneficiaries will not know that that their physicians, nurse practitioners, and physical therapists might be subject to the regulations of the DMEPOS program, unless "grandfathered." This will likely cause confusion, particularly where DMEPOS items might be provided through a physician's or other practitioner's office. Again, the "watch words" for us are clear, comprehensive information.

With respect to confusion occasioned by "grandfathering," the DMEPOS program allows certain special physician/practitioners (nurses, physician assistants, clinical nurse specialists, and physical therapists and occupational therapists in private practice) to receive payment for certain competitively-bid items furnished to their own patients as part of their professional services, even though they have not submitted a bid and have not been selected as a contract supplier. For example a physician's office devoted to orthopedic medicine, might make certain walkers and canes available for purchase through its practice.

Beneficiaries who are renting an item of DME, or oxygen and oxygen equipment, that meets the definition of a "grandfathered" item may elect to obtain the item from a grandfathered supplier. In this instance, beneficiaries need clear information about whether their physician/practitioner comes under the grandfathering provision of the DMEPOS program.

Advance Beneficiary Notices

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

A signed ABN indicates that the beneficiary was informed in writing prior to receiving the item that there would be no Medicare coverage due to the supplier's contract status and that the beneficiary understands that he or she will be liable for all costs that the non-contract supplier may charge for the item. In general, if a non-contract supplier in a CBA furnishes a competitively-bid item to any Medicare beneficiary, Medicare will not make payment unless there is an applicable exception, regardless of whether the beneficiary maintains a permanent residence in the CBA. In these circumstances, the beneficiary is not liable for payment unless the non-contract supplier in a CBA obtains an Advanced Beneficiary Notice (ABN) signed by the beneficiary.

Knowing Which Suppliers Are in Your Network and Supplier Calls

DMEPOS rules about supplier use of cell phones, pages, call-forwarding and other devices while away from their places of business are complicated and problematic. The rules establish a complex scheme for determining whether such use is permitted for purposes of defining working from one's place of business, as well as defining supplier networks within a CBA. While these rules are intended to tighten the definition of a supplier for purpose of the DMEPOS program, they are confusing. Many professionals conduct a great deal of their business and professional work by such devices. It is important that more clarity be provided in this regard. Further, a beneficiary will have little or no ability to know whether a supplier call is in fact in violation of such rules with respect to suppliers only making calls from their places of business and during business hours. And, of course, toll-free numbers add further complications.

Finding a Supplier

An emerging concern is that DMEPOS program rules that beneficiaries must follow in finding or acquiring a DMEPOS supplier will be burdensome. For example, CMS has sent notification letters to beneficiaries who may need to change suppliers in order for Medicare to pay for their equipment and supplies. The letter encourages each beneficiary to check with his/her supplier to make sure that the supplier meets the new requirements and provides instructions for the beneficiary to find another supplier, if necessary. Sorting through current supplier responses will be difficult. Equally difficult will be the prospect of finding an alternative provider. For persons who are ill, have diminished capacity, or have other mental or physical limitations, the challenge will be especially daunting.

Small Suppliers and Networks

In addition, the DMEPOS rules contain special provisions for small suppliers, including allowing them to form networks of small suppliers. It will be nearly impossible for beneficiaries to act with confidence in choosing a supplier, particularly with respect to understanding provider networks. There is fear in the beneficiary community about reliability of networks. Will entities with no experience in supplying DME utilize this approach to do business, and perhaps not provide the quality of service that the beneficiary expects?

The change may be a major issue when the beneficiary needs a repair or replacement and has difficultly identifying the particular supplier or supplier group that is responsible for the repair. This will only be compounded when a beneficiary is away from his or her supplier's service area network while traveling. In general, the beneficiary will have to know and make provision for getting such repairs or replacements made in advance as the DMEPOS rules require that such repairs and replacements are done by the supplier in the CBA in which the beneficiary maintains a permanent residence, unless the supplier or the supplier network has arrangements with certified suppliers in the areas in which the beneficiary is traveling.

Repair and Replacement in One's Competitive Bidding Area

Other confusion points, and a source for strong beneficiary education efforts, are the rules applicable to beneficiaries who are permanent residents within a CBA. These permanent residents are required to obtain replacement of all items subject to competitive bidding from a contract supplier, including replacement of base equipment and replacement of parts or accessories for base equipment that are being replaced for reasons other than servicing of the base equipment. Absent a strong effort to establish a comprehensive beneficiary education effort on behalf of the Medicare agency, beneficiaries in this circumstance may face serious access and payment challenges.

There may be situations in which a beneficiary from a non-CBA is visiting a CBA and needs a repair that cannot be done by the beneficiary's supplier. This beneficiary and the beneficiary's supplier may not be aware of the new rules. Again, a strong educational effort is needed to ensure that all beneficiaries are made aware of the need to utilize a contract supplier when they are in a CBA.

Conclusion

We remain cautious about the DMEPOS program. Its goals are laudable and we hope they will in fact lead to overall cost savings, while reducing fraud, waste, and abuse. Of major concern in this effort is that beneficiaries are able to get the services they need, that they are provided good information about the DMEPOS program, and that they have ready recourse when problems

arise. We worry, too, about suppliers that use the DMEPOS program as an excuse to make business decisions, unrelated to the new program, that adversely impact beneficiary access.

Thank you very much.

Alfred J. Chiplin, Jr., Esq.
Vicki Gottlich, Esq.
Senior Policy Attorneys
Center for Medicare Advocacy, Inc.

Mr. PALLONE. Thank you, Mr. Chiplin.
Ms. Schlichting.

STATEMENT OF NANCY SCHLICHTING

Ms. SCHLICHTING. Good afternoon, Chairman Pallone, Ranking Member Shimkus, Congressman Dingell and members of the subcommittee. My name is Nancy Schlichting. I am the President and CEO of the Henry Ford Health System in Detroit, Michigan, and thank you so much for the opportunity to testify.

I appear today on behalf of hospitals and health systems that own and operate their own durable medical equipment services. We are deeply concerned about the impact of competitive bidding on our patients and costs unless the program can be revised to protect our health care delivery model. The key value of our organizations is the ability to integrate and coordinate post-acute care with hospital care. Over the past 3 years we have worked as an informal coalition of hospitals and health systems in 22 States that have their own DME and other post-acute services as a tool for improving quality and safety and service for our patients while controlling costs. Durable medical equipment is one of many services housed within our health system that allow us to better manage and deliver patient care. All business units including DME are aligned to coordinate and integrate care at the best price in a very competitive marketplace with growing burdens of uncompensated care.

One of our primary goals is to provide a smooth transition between hospital and home so that patients can leave as soon as they are clinically ready and make beds available for new patients. In addition to reducing the length of stay, we also work to prevent unnecessary readmissions and to lower the use of the emergency department.

The ability to own and control virtually every aspect of patient care including DME is essential to our success. Members of our coalition are large and small and most are organized similar to Henry Ford Health System. Our coalition includes the Michigan Health and Hospital Association and many of the Nation's premier health systems such as the University of Michigan, University of Iowa, the University of Pittsburgh Medical Center, Advocate Health in Illinois, Aurora Health Care in Wisconsin, BayCare in Florida, the Cleveland Clinic and SUMMA Health System in Ohio, Banner Health in Arizona and Colorado, Providence in Oregon and Washington, and Meridian Health in New Jersey.

Two of our members, BayCare and the University of Michigan, have done studies showing that patient care and cost would be adversely affected by the competitive bidding as it is now structured. The Michigan study showed that the aggregate median length of stay for referrals managed by hospital-based services was 5.3 days compared to 6.8 days for referrals managed by non-hospital based services.

I want to note that we have not opposed competitive bidding. From the beginning our goal has been to advocate for the flexibility we need to manage patient care in a structure where pricing is the same for all DME providers in the area. In today's hospitals, patient discharges take place throughout the day. In many cases, the ability to send a patient home or into nursing care depends on the

availability of numerous items of DME: a hospital bed, surgical or diabetic supplies, wheelchair, a commode or oxygen. Coordinating the supply and delivery of DME is critical to avoiding extra days in the hospital, extra days that Medicare, Medicaid and private insurers will not pay for immediately, but these costs do get folded into the overall cost of health care.

When DME and other post-acute care is aligned with the hospital, we can respond to the demands of Medicare and private insurers for better care at a lower cost and less complexity for the patient and family. Having to use an outside DME supplier, or several suppliers in the case of complex patients, destroys this crucial alignment and perpetrates an inefficient and costly delivery system. Even though extra days in the hospital may not immediately and directly cost Medicare Part A more, the cost for unnecessary days remains in the health system and eventually everyone pays for it. Savings estimates for competitive bidding focus primarily on price reductions for durable medical equipment under Part B. What is left out of the picture are the increased costs that the hospital and within our health systems.

A number of health systems in our coalition are affected by phase one, which begins January of 2011, and very few have been awarded contracts for Medicare patients. Cleveland Clinic in Ohio and UPMC in Pennsylvania receive no contracts and are now shut of Medicare for DME services. Some other systems receive contracts for only one or two items. These results go in the wrong direction. For these health systems and hospitals, costs will be higher than necessary and support for families caring for elderly patients in the home will be lost. Instead of support and convenience, there will be 1–800 telephone numbers and multiple suppliers who often tell families calling to report malfunctioning equipment that they should go to their nearest ER.

Finally, we have been advised by CMS that the Secretary has no discretion in this matter and that there can be no administrative solution without additional legislation. While we have had good and constructive discussions with CMS, especially on the importance of integrated care as a tool for helping with issues of cost, CMS says that Congress must act. To address this problem, we have worked with Congressman Dingell and he has introduced H.R. 6095, giving qualified health systems that own and operate a DME entity the ability to continue to serve its patients at a reimbursement rate determined by the competitive bidding process for its region. We believe this is a limited, reasonable and commonsense remedy and we thank Mr. Dingell for his support and understanding as well as his remarks this morning. The bill will preserve savings associated with lower prices for DME services and allow us to preserve a critical patient management tool that allows us to save money and better serve the patients that come to us every day for quality medical care.

On behalf of our coalition, I ask for your support for Mr. Dingell's bill and will be pleased to answer any questions. Thank you very much.

[The prepared statement of Ms. Schlichting follows:]

Statement by Nancy M. Schlichting
President & CEO, Henry Ford Health System
Detroit, Michigan

For the
Committee on Energy & Commerce
Subcommittee on Health
Of the
U.S. House of Representatives

Hearing on Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program
September 15, 2010

Chairman Pallone, Ranking Member Shimkus, Congressman Dingell, Congressman Rogers and Members of the Subcommittee,

My name Nancy Schlichting. I am President and CEO of Henry Ford Health System in Detroit, Michigan.

I appear today on behalf of hospitals and health systems that own and operate their own Durable Medical Equipment services. We are deeply concerned about the impact of competitive bidding on our costs and patients, unless the program can be revised to protect our business model. The key feature of our organizations is the ability to integrate and align post-acute care with hospital care.

Over the past three years we have been working in an informal coalition with hospitals and health systems in 22 states that have developed their own DME and other post-acute care services as a way of improving quality and safety for our patients while controlling costs.

For us, Durable Medical Equipment is one of many services housed within our health systems that allow us to manage patient care effectively and efficiently. Henry Ford serves approximately 1 million patients in Southeast Michigan. We own and operate 6 hospitals, 27 regional medical centers and a 500,000 member HMO, which includes about 30,000 Medicare Advantage patients. Our 1,200 Henry Ford Medical Group physicians are salaried, and all business units, including DME, are aligned to coordinate and integrate care at the best price. We function in a very competitive marketplace with growing burdens for uncompensated care.

At Henry Ford, we work to get patients home safely from the hospital as soon as they are clinically ready, so that beds are available for new patients. We work to prevent

readmissions and lower use of the ER. We are able to do this while earning high marks for quality and patient satisfaction. The ability to own and control virtually every aspect of patient care, including DME and other post-acute care services, is essential to our success. Currently the Henry Ford DME services are integrated with Home Health, Hospice and our Nursing Homes. Overall approximately 90% of our Henry Ford DME services go to our own Henry Ford Patients in both hospital and clinic settings.

Members of our Coalition large and small and most are organized similar to Henry Ford. Our Coalition includes the Michigan Health and Hospital Association and many of the nation's premier health systems, such as the University of Michigan and University of Iowa, the University of Pittsburgh Medical Center, the Henry Ford Health System, Advocate Health in Illinois, Aurora Health Care in Wisconsin, BayCare in Florida, the Cleveland Clinic, Banner Health in Arizona and Colorado, Providence in Oregon and Washington, Meridian Health in New Jersey.

We estimate that patient care and costs at more than 200 hospitals would be adversely affected, unless the DME competitive bidding program can be reconfigured.

(A complete listing of Coalition Members is attached.)

I. Do We Oppose Competitive Bidding?

We have not opposed Competitive Bidding. From the beginning, our goal has been to advocate for the right of hospitals and health systems to use our own post-acute care services, including DME, to manage patient care. We have continued to ask for consideration for the DME companies we own and operate, so that we can continue to provide efficient care to our patients at a fair price. The American Hospital Association, Premier, Henry Ford and many other health systems have asked for help with competitive bidding since the rule was adopted in mid-2007. We are willing to accept the pricing determined by competitive bidding, but we question the wisdom of a rule will prevent our ability to own and control post-acute care as a strategy to improve care and reduce costs.

II. Secret of Good Care is in Alignment of Services

In today's hospitals, patient discharges take place throughout the day. We don't keep patients over the weekend, unless medically necessary. In many cases, the ability to send a patient home or into nursing care depends on the availability of numerous items of DME – a hospital bed, surgical supplies, diabetic supplies, a wheelchair, a commode or oxygen. Coordinating the supply and delivery of DME is critical to avoiding extra days in the hospital – extra days that Medicare, Medicaid and private insurers will not pay for immediately. But these costs do get folded into the overall cost of health care.

Where DME and other post-acute care is aligned with the hospital, we can respond to demands of Medicare and private insurers for better care at lower cost, with very high patient satisfaction. Having to use an outside DME company, or several companies in the case of complex patients, destroys this crucial alignment and perpetuates an inefficient and costly business model.

III. Case Studies on Cost

BayCare. During 2008, the HomeCare Division of BayCare Health System in Florida examined 37 cases where hospital discharge did not occur as expected. This was part of an internal Six Sigma study. In every case, delays were associated with an outside DME provider. These delays resulted in 79 additional days in the hospital for these 37 patients. Generally, we estimate approximately $1,500 per day for extended inpatient stays, including basic hotel services and the unavailability of the room for new paying patients.

Michigan. At the University of Michigan, a retrospective analysis of 1,695 hospital discharges needing home care services was evaluated for the months of October through December 2009. The aggregate median Length of Stay for referrals managed by the hospital-based home care services was 5.3 days, compared to a median of 6.8 days for referrals managed by non-hospital based home care providers (Home Health, DME and Home Infusion). Length of Stay was also higher for specific product lines (Home Health, DME, Home Infusion) where the U of M hospitals were required (by insurance contracts) to use outside suppliers. This study illustrates that hospital-based home care services results in an efficiency of 2,542 inpatient days for this time period. The U of M study estimated a difference in cost of care of at least $23.4 million. The U of M research also identified higher Emergency Department visits for patients referred to outside home care providers, as well as higher readmissions. (A copy of this research is attached).

III. Who Pays For Extra Cost?

Community costs for health care services concerns us all. This was a prime focus for the Patient Protection and Affordable Care Act adopted earlier this year. Key features of the new law call upon hospitals and health systems to integrate care by aligning services. Health care providers are encouraged to organize Accountable Care Organizations, Medical Homes, Health Innovation Zones in order to push ahead with integration and cost containment. The key strategy to meet these challenges is the close alignment of services and close alignment of incentives among all business units within our own health systems.

Even though extra days in the hospital may not immediately and directly cost Medicare Part A more, the cost for unnecessary days remains in the health system, and eventually everyone pays for it. Savings estimates for competitive bidding focus primarily on price reductions for Durable Medical Equipment under Part B. What is left out of the picture is the increased costs at the hospital and within our health systems.

We believe the competitive bidding program should be structured so that pricing stays the same for all DME providers, but at the same time, retain the ability of our hospital-based companies to serve Medicare patients.

IV. Current Status & Stark Legislation of 2008

Currently, competitive bidding for DME is being rolled out over several years. Phase I was delayed to January 2011 by legislation in 2008 that imposed a moratorium and 10% price cut for DME services.

Under the 2008 law, hospitals were allowed to supply the same DME items that physicians and other practitioners in outpatient clinics are allowed to supply as part of their "professional services." These items are crutches, canes, walkers, glucose monitors, infusion pumps and manual wheelchairs. While we are very grateful to Congress for recognizing that there is a problem under competitive bidding for hospitals and health systems, the new law did not go far enough. The types of services exempted from competitive bidding are not the services we require to manage needs of patients discharged from a hospital stay, or to prevent a readmission or to reduce Emergency Department visits.

A number of large and well-respected health systems in our Coalition are affected by Phase I, which begins January 2011. Very few of our hospital-based companies have been awarded contracts for Medicare patients. Among the health systems now shut out of Medicare for DME services are:

Coalition Member	**Products Bid On**	**Contracts Granted**	**Hospitals**
Cleveland Clinic (Ohio)	3	0	10
UPMC (Pennsylvania)	3	0	13 (20 total)
Carolinas Healthcare (NC, SC)	6	3	10
Advanced HC (NC,VA, TN, SC)	9	3	4 (1,200 beds)
SUMMA (Ohio)	8	3	9
BayCare (Florida)	7	1	N/A (17 Total)

These results will increase go in the wrong direction -- in health systems and hospitals in Phase I, hospital costs will be higher than necessary, and much-needed integration of care between the hospital setting and the home setting will be lost.

Michigan and other states will be included in subsequent roll-out phases of the Competitive Bidding Program.

V. The Solution - Proposed Legislation

We have been advised by CMS that there can be no administrative solution without additional legislation. While we have had good and constructive discussions with CMS, especially on the importance of integrated care as a tool for helping with issues of cost, CMS says that Congress must act.

We have had the pleasure of working with the Chairman Emeritus of this committee, Congressman Dingell and his staff. The bill provides a simple remedy to the problem. Under this bill, qualified health systems that own and operate a DME entity would be

allowed to continue providing DME to its patients and would be reimbursed at the rate determined by the competitive bidding process for its region. Specifically the bill will:

--Allow hospital-based DME companies to continue serving their entity's Medicare patients (inpatients and outpatients);

--Mandate that hospital-based DME companies be compensated at whatever price was established through Medicare's competitive bidding program;

--Ensure that hospital-based DME providers fully meet all credentialing and other requirements for Medicare DME contractors;

--Provide that the exemption would be limited only to those hospital-based DME companies providing such services in May, 2010 or earlier and only to patients of each DME's own health system;

--Allow hospitals and integrated health systems to continue full management of a key element of the hospital discharge, provision of DME services.

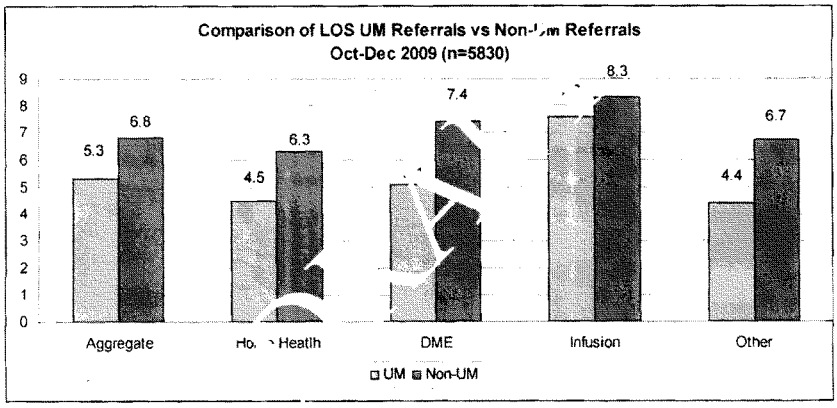
According to data available through CMS, we estimate that we represent about 1.5 percent of the market, so market presence is not a significant factor, and should not cause problems for the larger competitive bidding program. We know that there is concern about the competitive bidding process, and this is a larger policy issue for the Congress to determine. Our more limited and focused approach, as contained in Mr. Dingell's bill, H.R. 6095 will allow the competitive bidding system to proceed. It will preserve savings associated with lower prices for DME services. And, it will allow us to preserve a critical patient management tool that is demonstrated to save money and better serve the thousands of patients that come to us for quality medical care every day.

Thank you. I would be pleased to answer your questions.

Comparison of Length of Stay (LOS) for UM Referrals vs. Non-UM Referrals October – December 2009 (n = 5,830)

Background

The benefits of an extended continuum of care on hospital length of stay (LOS) and other metrics related to the transition of patients from the hospital to home has long been debated among proponents of hospital based home care entities. A retrospective analysis of discharge referrals (n=5830) needing home care services comparing the hospital LOS for hospital based home care referrals to non-hospital based home care referrals was evaluated for the months of October -December 2009. The aggregate median LOS for referrals managed by the hospital based home care services (n=2227) was 5.3 days compared to an median LOS of 6.8 days for referrals managed by non-hospital based home care providers (n= 3603) (p=.001). LOS of stay within specific product lines of home care (Home Health, DME and Home Infusion) was also lower for hospital based home care services. (Figure 1)



Patient Day Savings

Based on the LOS performance within these groups, improving the LOS for the non-hospital based referrals to the level represented by the hospital based home care services would result in an efficiency of 2,542 days (1.5 days (x) 1695). Annualized, this represents a potential efficiency of 10,168 patient days. Based on the current FY 10 median LOS of 6.07 days and $14,000 net revenue per discharge, the maximum potential efficiency in patient days represents approximately 1,675 additional discharges or approximately $23.4M in potential net revenue (Table 1)

% Target Potential	Patient Day Savings	Additional Discharges	Incremental Net Revenue
100%	10,168	1,675	$23.4M
75%	7,626	1,256	$17.5M
50%	5,084	837	$11.7M
25%	2,542	418	$5.8M

ED visits and Re-admissions

The aggregate ED visits were higher for the UM referrals vs. Non-UM referrals for the same time period (285 vs. 336, p = .001). Access to records of ED visits was only available for the UM ED and further analysis is needed to quantify visits that may occur at other hospitals.

Table 2: Comparison of ED visits within 30 days following discharge across service and provider groups

	UM	Other	p=
Aggregate	285/2227	336/3581	0.001
Home Health Care	131/1003	75/1129	0.001
DME	50/492	43/382	0.850
Home Infusion	81/593	18/184	0.152

Readmissions

Although numerically lower, there were no significant differences in readmissions rate within 30 days for UM referrals as compared to Non-UM referrals. The lower LOS for UM home care referrals does not negatively impact readmission rates. Further analysis is also needed to identify specific readmission diagnosis before determining whether readmission is related to previous discharge.

Table 3: Comparison of hospital readmission within 30 days following discharge across service and provider groups

	UM	Other	p=
Aggregate	596/2227	863/3581	0.224
Home Health Care	203/1003	228/1129	0.477
DME	114/492	80/382	0.981
Home Infusion	222/593	47/184	0.021

DME 2008–10 Coalition Membership By State
September, 2010

1. **Illinois**
   Advocate Home Care
   Resurrection
   Trinity
   Action Medical
2. **Wisconsin**
   ThedaCare
   Meriter
   Aurora
3. **Ohio**
   Cleveland Clinic
   SUMMA Health System
   St Rita's
   ProMedica
   Akron General Hospital
   NW Ohio Medical Equipment
   Great Lakes Home Health Services
4. **Pennsylvania**
   UPMC Home Care
   Vantage
   GSH Home Med Care Inc.
   Excela Health
   Great Lakes Home Health Services
5. **Florida**
   BayCare Home Care System
6. **Arizona**
   Banner Home Care
7. **Iowa**
   St. Luke's
   Trinity
8. **Colorado**
   Banner Home Care
   Centura
9. **Alaska**
   Banner Home Care
10. **Indiana**
    Community Home Health Services
11. **Maryland**
    Johns Hopkins
12. **Oregon**
    Providence Health Services
13. **Washington**
    Providence Health Services
14. **Tennessee**
    Baptist Memorial
    Advanced Home Care
15. **Minnesota**
    Fairview Health Services
16. **North Carolina**
    Carolina's Healthcare
    Advanced Home Care
17. **South Carolina**
    Carolina's Healthcare
18. **New York**
    Hi-Tech Medical Equipment
    Great Lakes Home Health Services
19. **Virginia**
    Advanced Home Care
    Sentara
20. **North Dakota**
    Great Plaines Rehabilitation Services
    MeritCare HealthCare Accessories Co.
21. **New Jersey**
    Meridian Health System
22. **Michigan**
    Alpena Oxygen & Equipment Co.
    Beaumont Home Medical Equipment
    Chelsea Community Hospital
    Covenant Healthcare VNA
    Allegiance (Formerly-Foote Health System)
    Genesys Health System/Ascension
    Hackley Healthcare Equipment
    Henry Ford Health System
    Aspirus Keweenaw Respiratory HME
    Lifespan Oxygen & Medical Equipment
    McLaren Visiting Nurses
    Mercy Memorial Hospital System
    MidMichigan Visiting Nurses
    Munson Home Medical Equipment
    Doctors Hospital of Michigan
    Oakwood Home Medical
    Sparrow Regional Medical Supply
    St. John Home Care
    U of Michigan Hospitals
    Michigan Health & Hospital Assoc.

Mr. PALLONE. Thank you.
Dr. Scanlon.

STATEMENT OF WILLIAM SCANLON

Mr. SCANLON. Thank you very much, Mr. Chairman. Chairman Pallone, Ranking Member Shimkus and members of the subcommittee, I am pleased to be here as you review the implementation of Medicare's durable medical equipment competitive bidding program.

I am an economist who has been involved in health policy research for 35 years. Until 2004, I was the managing director of health care issues at the U.S. General Accounting Office. I have also been a member of the Medicare Payment Advisory Commission, completing my second term this past May. My views today are my own and do not reflect those of any organization with which I have been affiliated.

Competitive bidding for durable medical equipment is one step in attempting to make the Medicare program a more efficient purchaser of services. There have been longstanding concerns about the level and growth of Medicare spending that growth while mirroring other sectors of health care has consistently exceeded the growth of GDP, inflation and the beneficiary population and imposes an increasing burden on taxpayers as well as on beneficiaries in the form of higher Part B premiums and cost sharing. It is essential to ask whether the program is being as efficient as possible in maintaining access to medically necessary services for its beneficiaries.

Efforts to make Medicare a more efficient purchaser have been underway for many years. Beginning in the early 1980s, Medicare payment methods for most services have been reformed in fundamental ways. DME payments stand out as an exception. This is despite a large body of evidence produced by the Department of Health and Human Services' Office of Inspector General and the GAO on how much Medicare payments exceed the prices charged to retail customers or a supplier acquisition costs. You have heard examples in today's testimonies. Efforts to refine Medicare DME payment levels administratively have proven very cumbersome. The burden of collecting sufficient retail price or acquisition cost data to change prices is formidable and only a limited number of prices have been changed over the years. Even when those data are available, setting an efficient price for the Medicare program is problematic. Medicare as a major purchaser should not have to pay retail prices to obtain beneficiary access. The advantages to suppliers of being able to sell to Medicare are likely sufficient to make them willing to offer Medicare a discount.

Competitive bidding offers an alternative to setting prices administratively which is less burdensome and more likely to result in better prices for the program. Suppliers have the incentive to offer better prices to be able to win a contract. The potential of competitive bidding has been demonstrated by the price reductions in the Texas and Florida demonstrations authorized by the Balanced Budget Act and in the two rounds of bidding under the Medicare Modernization Act authorized program.

Suppliers' willingness to offer prices is predicated on their expectation that winning a contract will result in a bigger market share. For this to be true, Medicare has to move away from its traditional any-willing-provider approach and limit the number of winning contracts. This is a significant change and there are legitimate concerns about potential disruptions and negative impacts on beneficiaries and providers. Taking steps to minimize such impacts and ameliorate them promptly is essential because the importance of making Medicare a more efficient purchaser cannot be ignored.

Two important steps to reduce some of these disruptions that have been taken are to award multiple contracts in each area and to award small businesses a very significant share of contracts. This preserves a range of supplier choices for beneficiaries. These provisions strike a balance between reducing potential disruptions and getting a better price for the program. Having more winners lowers bidders' incentives to offer lower prices. While having more winning contracts may result in somewhat higher prices in the short term, it also is likely to keep the program competitive over the longer term and guarantee savings in the future.

How the program is implemented on the ground as well as its design are incredibly important to minimizing disruption. As you have heard from Ms. King, there were legitimate concerns about the aspects of implementation in the first round of bidding in 2007. Some of the shortcomings identified in that first round may be the unfortunate but very common outcome of introducing such fundamental change. Substantial change requires a learning process on the part of providers and beneficiaries as well as CMS. This learning should not, however, be allowed to be a gradual process. It is important that CMS invest heavily in provider and beneficiary education and in monitoring the process of bidding and contract awards.

Requesting bids and securing better prices is only the first phase of making Medicare a more efficient, prudent purchaser of DME. Continued oversight to assure that access to and quality of products purchased meet expectations is also essential. Congress has required GAO to provide a report on the experience with the program including beneficiary access and satisfaction, quality issues, impacts on suppliers, especially small businesses, and opportunities for greater efficiencies. CMS needs to be able to answer those same questions on an ongoing basis. Simply identifying problems, however, is not sufficient. CMS also must be in a position to be able to resolve them as quickly as they are identified.

Let me end by underscoring, making the Medicare program a more efficient purchaser is critical to preserving access for beneficiaries and keeping the program more affordable for both taxpayers and beneficiaries. Competitive bidding for DME provides an opportunity to improve program efficiency. Competitive bidding itself, though, is only about setting the price. How one administers the purchasing of the products after contracts have been awarded is critical to assuring that the goals of access and quality are preserved. These things cannot be understated.

Thank you very much, Mr. Chairman. I would be happy to answer any questions you or members of the subcommittee have.

[The prepared statement of Mr. Scanlon follows:]

Testimony of

William J. Scanlon, PHD

On

Medicare's Competitive Bidding Program for Durable Medical Equipment:

Implications for Quality, Cost and Access

The Subcommittee on Health

US House of Representatives' Committee on Energy and Commerce

September 15, 2010

I am pleased to be here as you review the implementation of the Medicare Durable Medical Equipment Competitive Bidding Program. I am an economist who has been involved in health policy research for 35 years. Until 2004, I was the managing director of Health Care Issues as the US General Accounting Office. I also have been a member of the Medicare Payment Advisory Commission, completing my second term this past May. My views today are my own and do not reflect those of any organization with which I have been affiliated.

Competitive bidding for durable medical equipment (DME) is one step in attempting to make the Medicare program a more efficient purchaser of services for its beneficiaries. There have been longstanding concerns about the level and growth of Medicare spending. Medicare is the third largest component of federal spending currently amounting to approximately $500 billion a year. Furthermore, the rate of growth of Medicare spending, while mirroring other sectors of health care, has consistently exceeded the growth of GDP, inflation, and the beneficiary population[1]. This growth imposes an increasing burden on taxpayers as well as beneficiaries in the form of higher Part B premiums and cost sharing. It has also raised questions about the long-term affordability and sustainability of the program. Before any other consideration of how to address this situation, it is essential to ask whether the program is being as efficient as possible in maintaining access to medically necessary services for its beneficiaries.

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[1] CBO, *The Budget and Economic Outlook*, August 2010; CMS. *Medicare Enrollment: National Trends*, (http://www.cms.gov/MedicareEnRpts/Downloads/HISMI08.pdf)

Efforts to make Medicare a more efficient purchaser have been underway for many years. Beginning in the early 1980s, Medicare payment methods, such as paying reasonable costs or reasonable charges, widely recognized as inflationary, have been replaced. Prospective payment systems have been introduced for providers including hospitals, skilled nursing facilities, home health agencies, etc. along with a fee schedule for physician services. These payment methods have been refined repeatedly over the years with the initiative coming sometimes from the Congress and sometimes from the program itself. The Patient Protection and Affordable Care Act (P.L. 111-148, PPACA) includes multiple examples of such payment refinements.

The one area that stands out for not having payment methods reformed in a fundamental way is DME. Efforts to refine Medicare DME payment levels administratively have proven cumbersome and unworkable. Competitive bidding offers an alternative which is conceptually sound and appears feasible. As it does involve a significant shift in how Medicare beneficiaries will obtain DME products, there are legitimate concerns about potential disruptions and negative impacts on beneficiaries and providers. Taking steps to minimize such impacts and ameliorate them promptly is essential because the importance of making Medicare a more efficient purchaser can not be ignored.

My testimony today will review: some of the difficulties with attempting to use administered prices for DME; why I believe competitive bidding offers as suitable approach to establishing Medicare DME payment levels; and the need for intensive ongoing oversight to identify any problems that may emerge and the need for the capacity to address such problems in a timely manner.

Experience with Administered Prices Medicare payments for DME are predominately based on fee schedules constructed using submitted charges from the mid-1980s that have subsequently been updated for inflation. The absence of DME payment reform is in the context of a longstanding volume of evidence that Medicare was overpaying for many items of DME. The GAO and the DHHS/OIG repeatedly documented instances where Medicare payments exceeded retail prices that consumers could easily obtain from pharmacies and other suppliers. For example, GAO reported in 2000 that Medicare paid significantly more than the median retail price from a large sample of pharmacies for catheters, eyeglass frames, and lancets[2]. The differences respectively were: 24 percent, 21 percent, and 36 percent.

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[2] US GAO, *Medicare Payments: Use of Revised "Inherent Reasonableness" Process Generally Appropriate,* GAO/HEHS-00-79, July 2000.

Two administrative options are available for dealing with these inefficient prices—reducing the inflation updates and changing the fees for individual items. Modifying the inflation updates to lower prices for all products would reduce some of the excess payments. However, the difference between current Medicare payment and an efficient price that would maintain access may vary considerably across products. Across the board reductions create the risk over the longer term of access problems for selected items and could leave in place significant excess payments for others. For the longer term, it is important to have a means to adjust prices of individual items to efficient levels. Efforts to make such adjustments through an administrative process have been tried and proved too cumbersome to implement effectively.

The process, known as inherent reasonableness, involved the collection of retail price data from samples of suppliers. These data were then to be used to establish a new price through formal rulemaking. The time required for this process resulted in it being only used once to adjust the Medicare fee schedule for blood glucose monitors.[3] In this case, implementing the process took 3 years. While the Balanced Budget Act of 1997 (P.L. 105-33, BBA) modified the required rule making process to expedite fee schedule changes, the burden of collecting sufficient retail price information remained very significant.

Even if this process of collecting retail price information and setting fees had proven to be more manageable to set fees at a point in time, it would be a continuing challenge to keep fees at efficient levels over time. The nature of much technology means that prices and underlying costs are quite dynamic. Prices are highest when a product is first introduced and then decline over time. Initially products may be expensive reflecting the recoupment of development costs and less ability to spread fixed costs due to limited sales volumes. As products take hold and sales increase, prices drop as fixed costs can be spread over a wider base. In addition, economies of scale in production or cost saving production innovations may also be experienced. Competition from newly introduced substitute products can also pressure prices downward. The resulting pattern of prices falling over time for many products means that Medicare would have to devote considerable attention to keeping its payment levels current.

Having enough resources to undertake the ongoing information collection to identify what individual consumers currently pay at retail would not result in a set of efficient prices for the program. There is no single market price. There is instead a set of prices that vary depending on the purchaser. Being able to sell to Medicare beneficiaries may provide some advantages for a provider. There is greater demand for a provider's

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[3] US GAO, ibid.

products given that beneficiaries pay only a fraction of the price. There is more surety of payment compared to some other purchasers. Medicare is also cited frequently as a prompt payer. To the extent, providers value these advantages of selling to Medicare they may be willing to accept a lower price than charged individual retail buyers.

Competitive Bidding as the Alternative Competitive bidding provides an appropriate and feasible to establishing more efficient payment levels. It creates the incentives for providers to supply Medicare with the information needed to set prices as well as be willing to supply products at lower prices. It does involve moving Medicare away from an any-willing provider approach that maximizes beneficiary choice. However, DME is different in that it involves essentially products that are standardized. The same product purchased from different providers will be identical.

One of the GAO studies documenting Medicare overpayments hinted at the potential power of competitive bidding. The study issued in 1997 contrasted Medicare payments for oxygen services to those of the Department of Veterans Affairs (VA).[4] The VA used competitive bidding to select suppliers. It had more rigorous standards for what services must be provided and yet its per-month payment was approximately one half of Medicare's. Similar findings were reported in 2000 where Medicare prices for selected items were 72 to 259 percent higher than the VA's.[5] The conclusion should not be that Medicare can purchase DME in the same manner as the VA or obtain the same price. How beneficiaries in the two programs access services is very different. The comparison is instructive, however, in indicating that Medicare might gain moving away from an any-willing provider approach to a competition among providers for its business.

The power of competitive bidding comes from bidders' interest in increasing their market shares. Being a winner adds to the potential advantages of dealing with the Medicare program as demand by Medicare beneficiaries will be divided among fewer providers. How much can be gained in terms of more efficient prices depends on how competitive bidding is implemented. Implementation is also key to assuring there is no disruption in access to quality services. Equally important, given Medicare's importance as a purchaser, is that the process treat competitors equitably.

Experience to date has both demonstrated some of the potential benefits of competitive bidding for Medicare and provided opportunities to learn about appropriate implementation. The demonstrations in Florida and Texas, authorized by the BBA,

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[4] US GAO, *Medicare: Comparison of Medicare and VA Payment Rates for Home Oxygen,* GAO/HEHS-97-120R, May 1997.

[5] US GAO, *Medicare Payments: Use of" Inherent Reasonableness" Process Generally Appropriate,* GAO/HEHS-00-79, July 2000.

resulted in savings of approximately 19 percent.[6] Access to the services was unchanged with one exception being the use of portable oxygen equipment which experienced a 3 percent overall decline and a 12 percent decline among new users. While a number of potential factors may have been associated with the declines, they also highlighted the need for careful monitoring and having the ability to intervene if concerns arise.

Even more significant savings resulted from the two rounds of bidding in 2007 and 2010 as the program of competitive bidding required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173, MMA) has been implemented. Contracts awarded in the 2007 round were estimated to reduce payments by 26 percent.[7] The re-bidding in 2010 required by the Medicare Improvements for Patients and Providers Act of 2009 (P.L. 110-275, MIPPA) are estimated to result in even larger reductions of 32 percent.[8]

While a primary reason for introducing competitive bidding is to reduce excessive Medicare prices, it is important also to minimize any resulting disruptions. The program has been structured, as required by the MMA, to preserve beneficiary access to a range of suppliers and to maintain an important role for small businesses in supplying Medicare DME. The program thus strikes a balance between the objectives of beneficiary choice and small business protection and creating stronger incentives for bidders to offer lower prices. Having very limited numbers of suppliers would give bidders the strongest incentive to bid low for fear they would not be awarded a contract. It might generate lower prices in the short term, Allowing for more contracts to be awarded signals to potential bidders that winning a contract may result in less of a gain in market share and they may decide, therefore, to submit somewhat higher bids.

Increasing the number of contracts awarded may result in somewhat higher bids in the short term, but it also serves to make competitive bidding more robust for the longer term. A risk for a large purchaser, like Medicare, is to become too reliant on a limited number of providers. If issues arise with access, quality or the price of services and sufficient alternative provider capacity is not available, it may be difficult to resolve these issues promptly or effectively. Maintaining more providers in an area gives Medicare

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[6] Tommy Thompson, *Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,* Department of Health and Human Services, 2004.

[7] US GAO, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program,* GAO-10-27, November 2009.

[8] CMS Office of Media Affairs, "New Program Reduces Costs for Certain Durable Medical Equipment, Orthotics, and Supplies", *Medicare Fact Sheet,* July 1, 2010.

more flexibility to deal with a poorly performing provider. It also increases the odds that future rounds of bidding will have enough competitors to continue to secure significant savings. Given the market for DME, the likelihood of having enough future competitors would be high regardless. Medicare is a large purchaser of DME, but comprises less than one-third of the market.[9] Current suppliers who do not win a Medicare contract will be able to continue to serve other customers. New suppliers are also likely to be able to enter an area for future rounds of bidding as the requirements to become a qualified bidder appear manageable.

The experience of the first round of bidding in 2007 illustrates that minimizing disruption and concerns involves not just the program design, but the implementation on the ground. Concerns were raised about the adequacy of supplier and beneficiary education, the system for submission of bids, the handling of missing information and the disqualification of bidders. A GAO study released in November confirmed that some of these concerns were real.[10] That report also indicated that CMS had made progress in addressing these issues. Continued attention is essential.

Some of the shortcomings identified in the first round of bidding may be the unfortunate, but often common outcome of introducing such a fundamental change. Often when major changes have been made in Medicare, there have been transition periods where some blending of old and new policies coexisted for some time and allowed for a period of learning for providers and beneficiaries. Competitive bidding does not lend itself to such a phased introduction. A blending of policies over a period of time would significantly reduce the incentives for bidders to compete aggressively.

Substantial change requires a learning process on the part of providers and beneficiaries to understand new procedures and rules. It can also involve a need for learning and adaptation on the part of CMS to supply sufficient provider and beneficiary education as well as implement the new procedures and rules appropriately for its part. The approach to phasing specified in the MMA and PPACA involving adding new geographic areas to the program over time does give CMS the opportunity to work more intensively with the first areas and adapt implementation to reflect their experience. Learning should not, however, be allowed simply to be a gradual process. It is important that CMS invest heavily in provider and beneficiary education and in monitoring the process of bidding and contract awards.

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[9] CMS, *Historical National Health Expenditure Data,* http://www1.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp.

[10] US GAO, op. cit.

Ongoing Oversight Requesting bids, negotiating contracts and securing better prices is only the first phase of making Medicare a more efficient prudent purchaser of DME. Continued oversight to assure that access to and quality of products and services purchased meet expectations is also essential. In both the MMA and MIPAA, the Congress has required GAO to provide a report on experience under the program. Key areas to be examined include: beneficiary access and satisfaction; access or quality issues associated with suppliers new to a geographic or product area; impact on suppliers themselves, especially small businesses, including the costs of participation and the potential for greater efficiencies without affecting access or quality; and changes in the composition of products supplied within each of the Healthcare Common Procedure Coding System (HCPCS) codes.

Asking GAO to provide this report is important, but insufficient. CMS needs to be able to answer these same questions on an ongoing basis. Beneficiaries need clear information about their options for obtaining services and for redress if they incur any difficulties. They need to be informed about to whom to complain and those entities need to be equipped to respond. It is also important that CMS monitor utilization through analyses of claims to be able to detect declines in access or inappropriate substitutions of products. The latter is significant. GAO has noted in several reports on DME that literally hundreds of different items with a wide range of costs are billed under a single HCPC code[11]. Competitive bidding strengthens the incentive to supply lower cost items within a code. It is important for CMS to monitor the provision of items with HCPC codes and to be able to identify whether any substitution that is occurring is appropriate.

A fundamental question to be asked, not just about monitoring utilization of DME but all Medicare services, is whether Medicare has sufficient information about its beneficiaries and the services they receive to assess fully access. Given the investments being made in health information technology, there is an opportunity to improve the information Medicare receives about both the services delivered and the beneficiaries receiving them without a significant increase on the burden to providers. Taking advantage of this opportunity is an important element of making Medicare an efficient purchaser.

Simply identifying problems is not sufficient. CMS must be in a position to resolve them quickly as they arise. As noted previously, increasing the numbers of contractors in an area provides CMS more capacity for addressing a problem. If it proves necessary to suspend or terminate a contract, alternative providers should be available to fill the gap. In addition, CMS needs to do more than deal directly with a poor performing contractor,

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[11] US GAO, *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies,* GAO/HEHS-98-102, May 1998, and _____, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, GAO-04-765, September 2004.

informing beneficiaries using that contractor and assisting them in finding an alternative provider is also essential.

Conclusion Making the Medicare program a more efficient purchaser is critical to preserving access for beneficiaries and keeping the program more affordable. Competitive bidding for DME would only involve a small step toward overall program efficiency. But the potential benefits as indicated by the estimated savings of 32 percent from the 2010 bidding are too big to be ignored. Competitive bidding is a conceptually sound approach that fits the circumstances of DME provision and takes advantage of market forces. The introduction of competitive bidding does involve some disruptions and oversight is critical to address any issues arising after implementation. Through the requirements of the MMA to maintain beneficiary choice of providers and protect small business participation, a balance has been struck to reduce those disruptions. CMS can help make the implementation smoother through adequate education of providers and beneficiaries and needs to insure its investment in oversight is sufficient to promptly detect any problems requiring action.

Mr. PALLONE. Thank you, Dr. Scanlon, and we will have questions now from the members.

I guess I have to start with Ms. Lerner's doomsday scenario because she really did paint a picture. I mean, I am looking at the written testimony where she says we are going to drive thousands of qualified HME providers out of the Medicare marketplace and the result is a loss of ability to serve patients, layoffs, business failures, etc. I mean, obviously that is the concern, and of course, Mr. Chiplin was talking about how beneficiaries need to understand that their provider might change, and a lot of people are going to actually end up having a change in providers, so to speak.

But I wanted to go back to what Ms. Lerner said and I wanted to ask her and maybe Dr. Scanlon along those lines, I mean, basically the argument is that Medicare will contract with a reduced number of DME suppliers relative to the number of suppliers enrolled today, that competition will actually decrease under competitive bidding and over time this will actually lead to an increase in prices because there will be fewer bidders. Is that part of what you are saying, Ms. Lerner? I will start with you and then I will ask Dr. Scanlon the same thing, if you think that that is a convincing argument, and even if prices were to rise somewhat above the 32 percent savings projected by CMS for the round one re-bid, it would seem to me that prices would have a long way to go upwards to get back to current levels. So my question is, is this just a question of the competition? I mean, I know you mentioned all the problems with layoffs. Are you also arguing, Ms. Lerner, that competition is going to disappear and that ultimately we are going to end up—is that ultimately going to cost us more in the future or is it just the fact that we are going to have fewer suppliers and you are worried about the layoffs, so to speak?

Ms. LERNER. No, I think the competitive bidding bill is inherently anti-competitive. Studies show that 75 percent to 90 percent of the suppliers will not be able to compete in the marketplace and will be forced out of business or be acquired by existing DME. We are reimbursed by Medicare by product code. It doesn't matter the cost of the product, has no relevance to how we are reimbursed. So it is a competitive marketplace. We offer a better product. There are other clinicians that are——

Mr. PALLONE. The problem is—I know I am interrupting you. You know, we have heard all the testimony earlier about how there are so many of these providers out there. It is very easy to get in the business. They are charging too much. Medicare is losing money. There is fraud. I mean, obviously the competitive bidding was a response to that. I mean, you have to kind of tell me where you think we are on the spectrum. In other words, you don't see the competitive bidding as actually helping us in dealing with all this excessive cost; you think the opposite is going to happen?

Ms. LERNER. I absolutely think the opposite will happen. I think because of increased ER visits, readmissions to hospitals and not being able to discharge a patient, those are all costs that need to be factored in. I think Ms. Schlichting said length of stay is going to increase in a hospital because by the time you call five or six providers, one for the bed, one for the support surface, one for oxygen, you can't get them out of the hospital so they are going to stay

in the hospital longer. Hospital stay is much more expensive than home care.

Mr. PALLONE. Let me ask Dr. Scanlon to respond to this. She makes a good argument. What do you say?

Mr. SCANLON. I think it is important sort of to go back to one of the things that I mentioned, which is that there has been a balance struck in the way this program is being designed. Rather than being more aggressive in terms of trying to get the best price and awarding, say, only a single contract for a product in an area, there is going to be an award for multiple contracts and including sort of a proportion of those contracts going to small businesses. This is a part of maintaining sort of robust——

Mr. PALLONE. So you don't see this argument that competition is actually going to decrease and the costs will start to go up again?

Mr. SCANLON. I think there will be adequate competition over time. There will be a decrease in the number of suppliers but I think one of the questions we should be asking ourselves is, how many suppliers of DME should we have. There is a strong contrast between DME suppliers, the supply of DME sort of providers and suppliers, with the other types of providers in the Medicare program.

Mr. PALLONE. But you don't see the competition——

Mr. SCANLON. No. We have 100,000 DME suppliers compared to the—the next biggest number is 16,000 nursing homes.

Mr. PALLONE. All right. Let me ask Mr. Chiplin just because I am trying to keep to the time, although I am failing here, what about the whole education process? In other words, you know, obviously a lot of people are going to have a different provider. They may not know it. And I guess CMS has some kind of program to provide for this transition but what is your opinion of that? Is that good enough or do you want to comment on it a little bit?

Mr. CHIPLIN. Well, I applaud them for what they are doing. I know they have a very complex program to implement and to explain to beneficiaries. Our concern is that the beneficiary education effort to this point has been rather invisible. It is hard to find things, as I said, on their Web site. I think there needs to be more attention to those kinds of details about where you put beneficiary information and how it is made available to people. I think those are some of the fundamental things that can happen that will allow advocates such as our organization to have better access at trying to find the bits and pieces of information that can be translated into pamphlets and other things that would be of help to beneficiaries in understanding the program going forward. So I think one of the fundamental things with respect to beneficiary education, that it shouldn't be viewed as just an add-on the process but it should be an integral part of the rollout all the way across the board.

Mr. PALLONE. All right. Thank you. My time has run out.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I have not a lot of time and a lot of questions so I am going to try to go quickly.

Ms. Lerner, as an RN and as a provider of DME equipment, are all seat cushions equal?

Ms. LERNER. Not by a long shot.

Mr. SHIMKUS. And let me follow up. Do patients have different needs for different seat cushion arrangements?

Ms. LERNER. Of course.

Mr. SHIMKUS. And that kind of segues into the previous panel and this whole issue about lumping then in in the process, and I think many of us would argue that they should be separate. Let them compete but let them be separate based upon patient need.

Dr. Schlichting, I have been following Chairman Emeritus Dingell's bill. There are some compelling arguments in support of that legislation because in the bidding process—I don't know, I am not the person doing the bidding process but you would think—again, this is the difference between government and the competitive marketplace. If I was doing a bid contract and I needed stuff 24/7, I think I would write that into my bid process, but obviously CMS does not do that, and the concern is, no matter how the system—you just can't get the equipment on hand or the patient can't get it to leave in a timely manner through the hospital. Is that a simple synopsis of the concern? So you want to control that so you can move on?

Ms. SCHLICHTING. Well, you know, I think for any of us who have had to navigate through health care in this country, ways that we can make it simpler for patient and families and improve the efficiency by having that control of the continuum, we find that it has a real added value and that is what we are trying to preserve in this legislation.

Mr. SHIMKUS. Well, we definitely haven't moved in simplicity in the last 18 months.

Off the DME thing for a second. You are aware that the Administration's own Chief Actuary of Medicare estimated that 15 percent of hospitals will become unprofitable based upon the health care law. You are probably big enough that you are not one of them. Is that, am I safe to assume?

Ms. SCHLICHTING. Well, actually, one of the reasons we are profitable is the integration that we created Henry Ford. We have a salaried medical group. We have ambulatory and full continuum of care services, and we have a very high uncompensated care burden in Detroit as our flagship provider is one of the safety net providers in the State.

Mr. SHIMKUS. But you wouldn't dispute the 15 percent from the actuary talking about hospitals throughout the country who will probably have to close because of the provision?

Ms. SCHLICHTING. I can't speak to that, but I do think there will probably be more consolidation to create more efficiency of care.

Mr. SHIMKUS. Which is language for closures. Thank you.

Let me go to Dr. Scanlon real quick. Can't we put on quality measures for the bidding process to meet Ms. Schlichting's need for 24/7 delivery of equipment?

Mr. SCANLON. Certainly we can make that a requirement. I think on of the things that we need to think about are the contract specifications. What does it take to be a qualified provider. If that turns out to be one of the essential attributes, then we should make that a requirement. One of the instructive things about looking at the Veterans Administration is that they have used competitive bidding for a long time and they have actually have had stronger spec-

ifications in terms of the products they receive and services they receive than does the Medicare program.

Mr. SHIMKUS. And let me go, because of your expertise in government health care and also your experience in being an accountable. The health care law, do you believe it will lower costs or the deficit?

Mr. SCANLON. The deficit is a macroeconomic issue which is well beyond a health economist's purview so let me——

Mr. SHIMKUS. No, that is not true because there is a Medicaid expansion in the bill and it is projected by obviously the executive branch to be $10 million and we think more likely it will be $30 million, which is a burden to us, which is a burden to the States, especially who is a 50 percent payer.

Mr. SCANLON. I know, and I think I want to leave that to CBO in terms of——

Mr. SHIMKUS. I deal with the Army War College and we prepare them for Congressional testimony. One thing when I do talk to these soon-to-be senior leaders is that you better be prepared to answer any questions. You are an accountant, so I would expect—that is the advantage and disadvantage of coming before us.

Quickly, Mr. Chiplin, the final question for you is, if there are $575 billion cuts in Medicare reported by the Chief Actuary, is that harmful to senior citizens on Medicare?

Mr. CHIPLIN. Well, that is a very big number you just recited. It depends. I think the question really would be, where would those cuts come?

Mr. SHIMKUS. Well, they are coming from Medicare.

Mr. CHIPLIN. But I mean, even having said that, what particular services are cut, what access there might be that has been traded off in some——

Mr. SHIMKUS. Would it be safe to say that there is some concern?

Mr. CHIPLIN. Absolutely. That has been my testimony all along. I am not saying——

Mr. SHIMKUS. Right, and I got it. Thank you very much.

Yield back, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Shimkus.

Chairman Dingell.

Mr. DINGELL. Thank you, Mr. Chairman.

These questions to Ms. Schlichting. Are you for or against competitive bidding?

Ms. SCHLICHTING. Well, as part of this process, we have been very clear about the fact that we are not taking a position on competitive bidding. We accept competitive bidding as part of the process and we are trying to make sure that we have clarity around those organizations that are hospitals and health systems that have DME, that they will be able to continue to provide that integrated care.

Mr. DINGELL. Thank you.

Now, Congress has delayed competitive bidding for 18 months with a 10 percent price cut. In addition, Congress provided for an exemption for hospitals for certain products. Now, why is it that we need the legislation, H.R. 6095, that you have been discussing?

Ms. SCHLICHTING. There were two issues there. One is that it really only identified hospitals as opposed to health systems, and

we need broader inclusion of health systems in the legislation, and secondly, it didn't include all products frankly that hospitals and DME providers supply.

Mr. DINGELL. Would you submit to the committee the products that were not included that really should have been in there?

Ms. SCHLICHTING. We will be happy to do that.

Mr. DINGELL. Now, when I go into the hospital, I walk out, if I have had a broken leg or something, they give me a boot or they give me crutches or they hand me a cane and then they give me pills and such as that, or if I have had surgery on my eye they give me shields for the eye and things of that kind. If this is to be done by then some third party, how is that the hospital without the language of H.R. 6095 is going to properly be able to assign what it is I need and see to it that I have at expeditiously when I depart the hospital to go home?

Ms. SCHLICHTING. Hospitals may continue to provide certain elements that are absolutely essential for that patient to walk out the door but what they won't be able to do is provide those needed services in the home so that they get home safely, they have what they need. It is more complicated certainly for patients and families who often end up being the one that have to secure some of those needed supplies and equipment. So we believe that there is a much greater opportunity if our health systems have the chance to really fulfill all those needs.

Mr. DINGELL. Thank you. Now, the exemption that we have referred to earlier does not mean that hospital-based companies do not have to be accredited like everybody else. Isn't that so?

Ms. SCHLICHTING. That is correct.

Mr. DINGELL. Thank you. Now, CMS rules allow for smaller DME suppliers to form networks and to participate in Medicare as network suppliers. Why is this not a solution for hospital-based companies?

Ms. SCHLICHTING. Well, it basically still won't allow for the hospital-based companies to compete in terms of the size and scope of most of the hospital-based organizations so we believe again that the opportunity to create the integration at the hospital and health system level is very important.

Mr. DINGELL. Now, Ms. Schlichting, you have attached a study by the University of Michigan Health System. They looked at a longer length of stay for patients when they were outside the home, or rather when outside the home care providers were used. Can you elaborate on this and do you think that this is representative of the experiences of the other members of your coalition?

Ms. SCHLICHTING. We believe it is. In fact, the University of Michigan is much like Henry Ford. It is a very large health system. And they looked at considerable detail around this over a three-month period, and another of our members, BayCare, also studied the impact, and in cases where the hospital did not use its own DME but was required by insurance contracts to use outside suppliers, there were extra days in the hospital, higher readmissions and more use of the ER as compared to outside providers.

Mr. DINGELL. Thank you.

Now, Dr. Scanlon, how many major suppliers of durable medical equipment will there be in this country because of the concentra-

tion of power and market in the hands of a few dominant distributors of these commodities under the form that we are discussing today? Just give me the number, if you please.

Mr. SCANLON. I am afraid I don't have the number. I can say that it is totally a function of how CMS awards the contracts, what kinds of targets they set in terms of how many——

Mr. DINGELL. Then answer this question. First of all, the number will be reduced, yes or no?

Mr. SCANLON. Yes, it will. It is 100,000 now.

Mr. DINGELL. And what will that do with regard to competition elsewhere in the industry with regard to other people? There will be less competition for their business because there are going to be a few very dominant larger suppliers, right?

Mr. SCANLON. I think there will be fewer suppliers and some reduction in competition but there may still be ample competition to keep prices at reasonable levels. Medicare is about a quarter of the durable medical equipment market, so three-quarters of the revenues are coming from other purchasers.

Mr. DINGELL. My time is running out, and this question is very important. But then we are going to confront a situation where there will be just a few dominant suppliers in any of the regional markets that are being created by this matter by concentrating the power in the hands of just a few suppliers. For example, in our Detroit area there will probably only be one. Maybe in New York there will be five or six. But that will be instead of a much larger number of people we have doing business there. Isn't that going to be a consequence of this?

Mr. SCANLON. I think that again it is going to depend upon how CMS chooses to award contracts, what kinds of requirements they have for local presence because a large company may be able to supply a very large share of the market to mail order but may not be able to supply sort of things locally when it requires a physical presence in each area.

Mr. DINGELL. There is nothing to say that one of these near monopolists is not going to all of a sudden decide well, by golly, I think this would be very nice if we all of a sudden went into the mail order business, and using that the power that they have of the economy for large sales stimulated by their recognition under Medicare they can all of a sudden then dominant not only the market for Medicare supplies but also the mail order supplies because of the market power they have and do like the Japanese do, subsidized because of the monopoly in their own market.

Mr. SCANLON. Again, I think that that scenario depends upon sort of how CMS chooses to award contracts——

Mr. DINGELL. Are either——

Mr. SCANLON [continuing]. What kinds of specifications they have that would allow the transfer of——

Mr. DINGELL. Are either of these scenarios that I am discussing illogical or improbable?

Mr. SCANLON. They are not impossible. I would say that I do not expect them in the intermediate term.

Mr. DINGELL. So we can figure that perhaps the millennium has descended upon us. The good Lord will assure us that these unto-

ward events will not be visited us by the monopoly that we are creating. Am I right or wrong?

Mr. SCANLON. I think you are right.

Mr. DINGELL. Thank you.

Thank you, Mr. Chairman, for your courtesy.

Mr. PALLONE. Thank you.

Thank you again, I mean, obviously this is very spirited because there are areas where you agree and there are other areas where you disagree, but I think the bottom line is that this was very helpful to us today in terms of oversight of what is going on with this issue. Again, you may get additional questions from us, usually within 10 days, from the clerk in writing and get back to us as soon as possible. I think that this hearing today was extremely helpful in terms of knowing some of the problems but also we are going to have to dig a little deeper as well. So thank you very much.

Unless anyone else has any questions, without objection, this hearing of the subcommittee is adjourned. Thank you.

[Whereupon, at 1:30 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement
Honorable Ranking Member Joe Barton
Subcommittee on Health
Hearing on DME Competitive Bidding
Wednesday, September 15, 2010

Thank you, Mr. Chairman. First, I would like to welcome the witnesses who will testify today. We appreciate your being here to educate the committee today about competitive bidding in the Medicare program

Competition works, and it works every day in nearly every facet of American life except government and health care. Only at that crossroad do people come up with charges like $100 for the famous "mucus recovery system," also known as a box of Kleenex.

That's why I think that the competitive bidding program has the potential to save the American taxpayer and Medicare beneficiaries an enormous amount of money. We can do this by letting the suppliers of durable medical equipment compete to offer the best price—an idea far better than having prices set by an all-knowing Washington bureaucracy.

I recognize that some of our witnesses today may express doubts about the program. But we must trust that free market principles will both lower the cost of these products and save the American taxpayer money. Indeed, CMS has calculated that it will yield savings of an average 32 percent. And I know

everyone in this room agrees that health care costs are growing at an unsustainable rate. Thus, I believe we must continue with this program that will save both beneficiaries and the taxpayer money.

I am happy that we are finally having a health care hearing on something that will save the taxpayer money. But I must also note that next week is the six-month anniversary of the passage of the Majority's disastrously expensive health care law.

Reports of problems in Obamacare abound, but has this committee had a hearing on its implementation? No. In fact, this subcommittee has held 15 hearings since its passage, but not one of them dealt with the most radical change to every American's health care in generations. The same is true of the subcommittee on Oversight and Investigations: 7 hearings since passage—not one on Obamacare.

As all of us have noticed lately, people back home are experiencing the unhappy reality of the federal government's health care takeover. Many of them seem to

prefer a congressional Majority that wants to get the truth from the Obama administration about what's gone wrong so it can be fixed.

I know the seniors in my district are completely clear about their desire to have us look into the administration's plans to cut $575 billion from Medicare.

They also want to know about statements by the Chief Actuary of Medicare that under Obamacare, Medicare providers "could find it difficult to remain profitable" and might "end their participation in the program."

And they are telling me that we better find out the facts of the law's new costs and regulations—new burdens that the Wall Street Journal reported last week would result in coming premium increases for Americans.

And any American concerned about the disastrous spending policies of this administration and the current Majority would want oversight over recent revelations that after passage of Obamacare, health care spending is projected to increase *more* than CMS had projected before passage.

Time and time again the Democrats promised us that the health care law would perform miracles if passed.

Seniors were told the law would strengthen Medicare, only to see reductions to the program spent on new entitlements.

Americans were told the cost curve would be bent down, only to see the Administration's own actuaries report it will continue to go up.

Everyone was told that if they liked their current coverage they could keep it, only to see that the law encourages employers to drop coverage, that health insurers will pass along increased costs through increased premiums, and that every plan will be subject to a host of costly new federal rules and restrictions.

Where is the oversight? Where are the hearings? I know that the American people would rather a Congress that is run by those willing to fix their mistakes than one that tries to sweep them under the rug as an election nears.

I'll wrap up by saying that the subject of this hearing—competitive bidding in the Medicare program -- is important. But I also ~~,I~~ think all of us owe a duty to our constituents to point out why we're really here today: the Majority is looking to talk about anything except the mounting failures of their health care law. And instead of trying to see how we can fix the law, the Majority wants to ignore it. I believe that is unacceptable, and I am sure the American people agree.

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STATEMENT FOR THE RECORD

SUBMITTED TO THE

Energy and Commerce Health Subcommittee

United States House of Representatives

on

Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access

September 15, 2010

AARP
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WASHINGTON, D. C. 20049

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AARP appreciates the opportunity to present our views on Medicare's Competitive Bidding Program for Durable Medical Equipment. Medicare is a vital component of financial security for older Americans and many Americans with disabilities, and we must ensure that the program continues to remain a viable and responsive part of retirement security for all Americans. AARP is committed to the Medicare program and believes it is essential that Congress continue to strengthen and improve Medicare for current and future beneficiaries.

Medicare Durable Medical Equipment Benefit

Medicare covers many types of assistive technologies, known as durable medical equipment (DME), that improves beneficiaries' health and functioning. The most common are mobility devices such as wheelchairs and walkers. Durable medical equipment, orthotics, and supplies (DMEPOS) are reimbursed under Medicare Part B and the program is estimated to have spent $8.9 billion on DME in 2009.

Unfortunately, reports of overpayment and of fraud and abuse have become associated with the Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) benefit. For example, the Government Accountability Office has reported to Congress for more than a decade in numerous reports that Medicare paid higher than market rates for DMEPOS, thus increasing costs to the Medicare program and to Medicare beneficiaries.

Similarly, over the years, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) has uncovered strategies that medical equipment suppliers had used to circumvent billing controls and potentially defraud the Medicare program. The OIG has also identified certain types of durable medical equipment that are particularly vulnerable to billing abuses. For example, in 2004, the OIG estimated that Medicare and its beneficiaries paid $96 million for claims that did not meet Medicare's coverage criteria for any type of wheelchair or scooter and that they overspent an additional $82 million for claims that could have been billed using a code for a less expensive mobility device.

Congress has taken a number of steps to deal with these issues, including establishing the DMEPOS Competitive Bidding Program. Congress passed legislation to implement this program after HHS conducted competitive bidding demonstration projects in Polk County, Florida and San Antonio, Texas that resulted in an average 20 percent savings for Medicare. In addition, HHS reported that data from demonstration projects indicate that beneficiary access and quality of services were essentially unchanged. It is important to note that savings to the Medicare Part B program also result in reduced out-of-pocket costs to Medicare beneficiaries who utilized DMEPOS services and lower Part B premiums.

DMEPOS Competitive Bidding Program

AARP believes that competitive bidding should be used for pricing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), as long as quality and access are not compromised by the competitive bidding process. If the Competitive Bidding Program achieves the goal of setting more appropriate payment amounts for DMEPOS items, it will result in reduced beneficiary out-of-pocket expenses as well as savings to taxpayers and to the Medicare program.

CMS estimates that the program will save Medicare $17 billion over 10 years, which in turn will produce savings for Medicare beneficiaries. For example, CMS estimates that competitive bidding will result in a 33 percent reduction in Medicare payments for oxygen concentrators. Currently, Medicare pays an average of $173 for oxygen concentrators – that amount would drop to $116 under competitive bidding.

Some have voiced concern that, particularly in the early stages, implementation of these provisions could adversely affect Medicare beneficiaries' access to DMEPOS. AARP believes CMS should closely monitor Medicare beneficiaries' access to DMEPOS. At the same time, CMS should strictly enforce regulations on accreditation and minimum quality standards for DMEPOS suppliers in order to deter unnecessary utilization of items, while ensuring Medicare beneficiaries

have access to safe, high-quality, medically necessary, and appropriate DMEPOS.

AARP urges Congress to provide the necessary oversight to ensure quality and access for beneficiaries as CMS implements this new program. Specifically:

- CMS should ensure that the competitive bidding process provides for exact individual specifications for DMEPOS. The agency also should monitor and publicly report on whether Medicare beneficiaries and the DMEPOS program are receiving appropriate quality of service and value from DMEPOS.

- CMS should give Medicare beneficiaries some assurance that the contract suppliers under the Round One Rebid will be fully capable of meeting their needs, which necessarily means they must be willing and able to furnish a sufficient range of high quality DMEPOS products. CMS should have a process in place to address a situation in which a supplier is unable to meet a beneficiary's needs for equipment or supplies.

- CMS should ensure that Medicare beneficiaries living in the nine Round One communities who may have to choose a new Medicare supplier have the necessary information to maintain Medicare coverage. CMS should work with local partners and health care providers to inform beneficiaries about the changes, as well address any problems in a timely manner if they arise.

On behalf of AARP's millions of members, we thank the Subcommittee for holding this hearing. AARP is committed to fighting fraud and abuse in our health care system and particularly in the Medicare program. In addition, we continue to seek ways to ensure that beneficiaries' premiums and out-of-pocket expenses are kept affordable, while maintaining access and quality. AARP is also committed to ensuring that older adults and persons with disabilities have the services and supports they need, including DMEPOS, to live independently in

their homes and communities. AARP believes the DMEPOS Competitive Bidding Program – if structured correctly – can achieve these multiple objectives. We look forward to working with Congress and with the Department of Health and Human Services to rid our system of abuse while ensuring that all beneficiaries have access to quality health care and other benefits covered by the Medicare program.

American Hospital Association

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September 13, 2010

The Honorable John D. Dingell
Chairman Emeritus
Committee on Energy and Commerce
2328 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Dingell:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) is pleased to express our support for H.R. 6095, legislation to ensure community hospitals are able to provide quality durable medical equipment (DME) services to the patients they serve.

As you may recall, the *Medicare Modernization Act of 2003* directed the Centers for Medicare & Medicaid Services (CMS) to establish a competitive bidding process for DME, prosthetics, orthotics and supplies to reduce Medicare's costs for these products and services. While Congress temporarily delayed this program when it passed the *Medicare Improvements for Patients and Providers Act of 2008*, the *Patient Protection and Affordable Care Act of 2010* reinstated the program and expanded it to 21 additional metropolitan statistical areas.

The AHA remains concerned that, as this program moves forward, patient care could suffer if community hospitals do not have the ability to provide these important services to their patients. H.R. 6095 would permit hospitals to accept the competitively bid price without participating in the competitive bidding process. In addition, H.R. 6095 would allow hospitals to continue to directly provide equipment and supplies to their patients during a hospital stay and upon discharge to their homes and communities.

Thank you again for your efforts on behalf of America's hospitals. We look forward to continuing our work with you on this important issue.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President

PREMIER

September 10, 2010

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The Honorable Henry Waxman
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The Honorable Joe Barton
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The Honorable Frank Pallone, Jr.
Chairman, Subcommittee on Health
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The Honorable John Shimkus
Ranking Member
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The Honorable John Dingell
Chairman Emeritus
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United States House of Representatives
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Dear Chairmen Waxman, Pallone and Dingell and Ranking Members Barton and Shimkus:

On behalf of the more than 2,400 nonprofit hospitals and healthcare systems nationwide allied in Premier, many of which are responsible for providing Medicare patients with durable medical equipment, I am pleased to offer our support of H.R. 6095, legislation to preserve integrated care for durable medical equipment (DME) under Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies competitive bidding program.

This bill would allow qualified health systems, including many Premier members, to continue providing DME to their patients if they agree to accept the Centers for Medicare & Medicaid Services (CMS) negotiated price for the equipment and meet certain conditions.

Resuming Medicare's current competitive bidding program without making this change could interfere with these hospitals' ability to provide coordinated and timely DME services to their patients. In-house suppliers provide critical support to hospitals for the efficient management of the discharge process. Delays in securing DME through outside vendors often results in delayed discharge, ultimately driving up costs as hospitals are not compensated for the extended hospital stays.

H.R. 6095 would allow hospitals with DME-related entities to provide services regardless of receiving or not receiving the bid for those Medicare referrals outside of the hospital discharge setting. We think the legislation is a commonsense reform to an otherwise rigid competitive bidding structure.

Thank you for your consideration of this important matter.

Sincerely,

Blair Childs
Senior vice president, Public Affairs

ConvaTec
Written Testimony to the House Energy and Commerce Committee
Health Subcommittee

Hearing on "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access"

Submitted by: Joseph Rolley
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September 15, 2010

Introduction and Overview

ConvaTec appreciates the opportunity to submit written testimony for the record regarding "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access." ConvaTec is a U.S.-based leading developer and marketer of innovative medical technologies that have helped improve the lives of millions of people worldwide. With four key business divisions – Ostomy Care, Advanced Wound Therapeutics, Continence and Critical Care, and Infusion Devices – ConvaTec products support patients and health care professionals from the hospital to the community health setting. From its global headquarters in Skillman, New Jersey, the company oversees more than 8,000 employees, in over 90 countries, serving consumers and their health care professionals on six continents.

Competitive Bidding Overview

ConvaTec strongly supports patient access to high-quality affordable medical devices and prosthetics to meet their health and medical needs. Further, ConvaTec supports the policy goal of ensuring fair and equitable pricing of medical devices for patients and health professionals.

Competitive bidding of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), as a cost containment/savings initiative, has been an issue of great interest and activity by both the Executive and Legislative branches for several years. The current DMEPOS competitive bidding program in place for medical device suppliers has caused concerns relating to both patient access to products and the impact on device suppliers, and, as such, new federal legislation was introduced to seek repeal of this provision and replace it with targeted cuts to fee schedules of certain categories of medical devices. Further, the Government Accounting Office (GAO) has begun a study to assess competitive bidding for medical device manufacturers.

ConvaTec appreciates concerns raised regarding the current DMEPOS Competitive Bidding program, but believes efforts to replace this initiative with cuts to fee schedules must be carefully crafted to fairly and equitably distribute the impact of reductions to the fee schedule, while ensuring patient access to high-quality products. In addition, ConvaTec strongly believes expanding competitive bidding into the manufacturing sector is untenable and would result in a reduction in patient and provider choice of appropriate products for their use.

ConvaTec
Written Testimony Submitted to the
Health Subcommittee of
House Energy and Commerce Committee
September 15, 2010

As this Committee continues to explore policies to address ways to ensure access to the medical devices patients need, while containing costs, some solutions being considered are neither simple nor equitable. ConvaTec would like to respectfully identify several areas of particular concern.

An Across-the-Board Cut is Not an Equitable Solution

The medical device industry is comprised of a wide range of manufacturers and suppliers, varying significantly in the size of companies, range of products, categories of merchandise, and degree of profit margins. H.R. 3790, *Repeal of Medicare DMEPOS Competitive Acquisition Program*, has been introduced in the House of Representatives to repeal competitive bidding and replace it with cuts to fee schedules of some categories of medical devices. While well-intentioned, alternatives to competitive bidding, such as an across-the-board cut to the medical device fee schedule, will negatively impact some device categories more than others.

Across-the-board cuts that do not take into account unique differences and value inherent in those categories may severely impact patient access to the products they need. For example:

- Ostomy products are medical devices specially fitted by a health care professional to temporarily or permanently manage and/or reestablish intestinal or urinary tract function, restore an essential activity of daily living, and improve a patient's quality of life. Ostomy prosthetics are customized to the clinical needs of individual patient and, as such, are not easily interchangeable supplies, like gauze or bandages.
- Ostomy products are defined as prosthetics under Medicare.
- Ostomy products are reimbursed by Medicare as medical supplies, rather than durable medical equipment (DME,) because they are daily-use disposable, and, as such, supplier profit margins for these types of products are low, relative to other DMEPOS categories. In addition, these products are already competitively priced among the various ostomy products available.
- Should ostomy products be subject to across-the-board fee schedule cuts, few suppliers would be able to sustain the profit margins necessary to maintain their inventories – forcing patients to find cheaper, lower-quality substitutes from the few suppliers that remain. This could seriously compromise patient care.

Competitive Bidding Complexities and Inequities

The current competitive bidding model involves bidding among durable medical equipment (DME) suppliers -- manufacturers are not directly involved in the process. The GAO is exploring the possibility of extending competitive bidding to encompass manufacturers. While in theory this may appear to be a more direct way of reducing prices, it would present numerous challenges and inequities, if it were to move forward. Complexities in instituting a manufacturer-based competitive bidding program include:

- Many manufacturers sell through distributors and not directly to suppliers.
- Once the manufacturer sells a product to a distributor, there are no mechanisms in place to control the price the supplier pays the distributor; yet, manufacturers would be required to establish selling prices for downstream suppliers, without the ability to influence the suppliers' acquisition cost.
- Manufacturers would be forced to establish costly and extensive systems for price reporting and rebating to business entities that have no direct relationship to the manufacturer.
- Competitively bid contracts with manufacturers would have to be brand-specific (e.g., Engenex™), not category contracts (negative pressure wound therapy). This will result in brand winners and brand losers and, eventually, fewer and fewer brand choices for patients and providers.
- The current system of bidding by Healthcare Common Procedure Coding System (HCPCS) code would have to be abandoned, because manufacturers sell brands, not categories of products.

Conclusion

ConvaTec appreciates the Committee's interest in providing appropriate cost containment/savings initiatives to ensure patient access to appropriate medical devices and products. We urge the Committee to partner with the medical device industry in determining fair and equitable initiatives that would provide savings, without compromising patient care or quality of life. Further, we strongly urge the Committee to exclude manufacturers in any future competitive bidding model – such an addition would ultimately lead to fewer patient choices and would cripple the medical device industry that seeks to provide high-quality, cost-effective products and devices to patients and health providers.

Thank you for the opportunity to submit comments.

About ConvaTec:

ConvaTec is a U.S.-based leading developer and marketer of innovative medical technologies that have helped improve the lives of millions of people worldwide. With four key business divisions – Ostomy Care, Wound Therapeutics, Continence and Critical Care, and Infusion Devices – ConvaTec products support health care professionals from the hospital to the community health setting. From its headquarters in Skillman, New Jersey, the company oversees more than 8,000 employees, in over 90 countries, serving consumers and their health care professionals on six continents.

Monday, July 19, 2010, 5:43pm EDT | Modified: Monday, July 19, 2010, 5:46pm

Lincare picks up Medicare contracts in Miami, Charlotte

TAMPA BAY BUSINESS JOURNAL

With a better than expected quarterly gain in net income, **Lincare Holdings Inc.** said it agreed to provide oxygen equipment in Miami and Charlotte, N.C., under a new bidding system for awarding Medicare contracts.

The announcement came with a warning from Lincare (NASDAQ: LNCR), a respiratory therapy provider headquartered in Clearwater, that the pricing mechanism used by federal regulators to determine the payment rates for oxygen equipment in those markets and others is fundamentally flawed and that may lead to poorer patient care.

The Centers for Medicare and Medicaid Services took competitive bids earlier this year to determine the price that Medicare will pay for certain durable medical equipment, prosthetics, orthotics and supplies in nine cities, including Miami, Charlotte and Orlando. The program replaced Medicare's existing fee schedule amounts with market-based prices.

Many providers submitted rates that are unsustainably low, and some of the contracts have been awarded to companies that do not currently serve patients in the selected markets, John Byrnes, Lincare's chief executive officer, said in a release. Overall, there was a 32 percent price reduction for stationary oxygen equipment, a bigger cut than expected.

Lincare's bids to provide the equipment were higher than the new rates established for the markets, the release said. Lincare bid 19 percent more than the rate established by CMS for Charlotte and 16 percent more than the rates established for Miami.

"We decided to execute the contracts we were offered because we believe we can support the Medicare beneficiaries in those markets by subsidizing their care with the resources we have available to us as a national company," Byrnes said. "We have serious concerns about the care that will be available to similar patients in the other seven markets. Lincare has no current plans to acquire contracts from winning bidders in those seven markets."

Lincare also reported net income of $46.4 million, or 47 cents a share, for the second quarter of 2010, compared with net income of $33.5 million, or 33 cents a share, for the same period a year ago. Earnings were a penny a share better than the 46 cents estimated by 10 analysts.

Revenue for the three months ended June 30 was $418.4 million, a 10 percent increase over revenue of $380.4 million for the year-ago period.

For the six months ended June 30, Lincare posted net income of $90.1 million, or 92 cents a share, on revenue of $828.4 million. In the year-ago period, Lincare's net income was $59.5 million, or 56 cents a share, on revenue of $752 million.

Congress of the United States
Washington, DC 20515

August 11, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Room 314
Washington, DC 20201

Dear Administrator Berwick:

We are writing to request that the Centers for Medicare and Medicaid Services (CMS) disclose to us the list of the providers, by product category, whose bids were used to calculate the single payment amounts under the re-bid of Round One of the competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Without knowing the identity as well as the appropriate overall qualifications of these providers, we cannot evaluate the program's impact in terms of quality and access to care for seniors we represent.

As you are aware, during the initial Round One bidding process in 2008, a significant number of providers who signed contracts were later determined to be sufficiently flawed in their qualifications. Among the problems that surfaced were that bidders did not have the financial resources to deliver services to a larger number of patients or they had no experience in the product categories for which they were awarded bids. Additionally, it was discovered that several "winners" did not have the required certification or licensure to provide the devices and services for which they were awarded contracts, or they simply did not have a physical location in the area. It was for these reasons and others that Congress delayed implementation of the program and required a re-bid.

We want to ensure that qualified providers have been chosen to provide these items and services to our constituents. Our district hospitals, physicians and elders who rely on home medical equipment services will be dependent on the winning bid companies for these critical in-home products. The healthcare community will again have very serious problems if it turns out once more that these companies are unable to provide sufficient access to quality items and services or do not have the financial ability to operate under the new contracted rates.

We understand that it is the intent of CMS to release the names of the winning providers in September after it has finalized contracts with these companies. Given the concerns with this process in the past, we seek this information now in order to evaluate the Round One re-bid in an open and transparent manner.

Accordingly, we respectfully request that CMS provide to us a list of the names of the suppliers, product categories and competitive bidding areas for each of the suppliers whose bids were used to determine the payment amounts no later than Friday, August 20, in order to enable us to appropriately assess the program's ability to meet the medical needs of our constituents.

We look forward to receipt of the requested information promptly, and thank you for your cooperation in enabling us to protect the health interests of our seniors.

Sincerely,

Jason Altmire

Ralph Hall

Bob Inglis

Michael T. McCaul

James R. Langevin

Bill Posey

Patrick J. Tiberi

Ron Paul

Todd W. Akin

Bill Shuster

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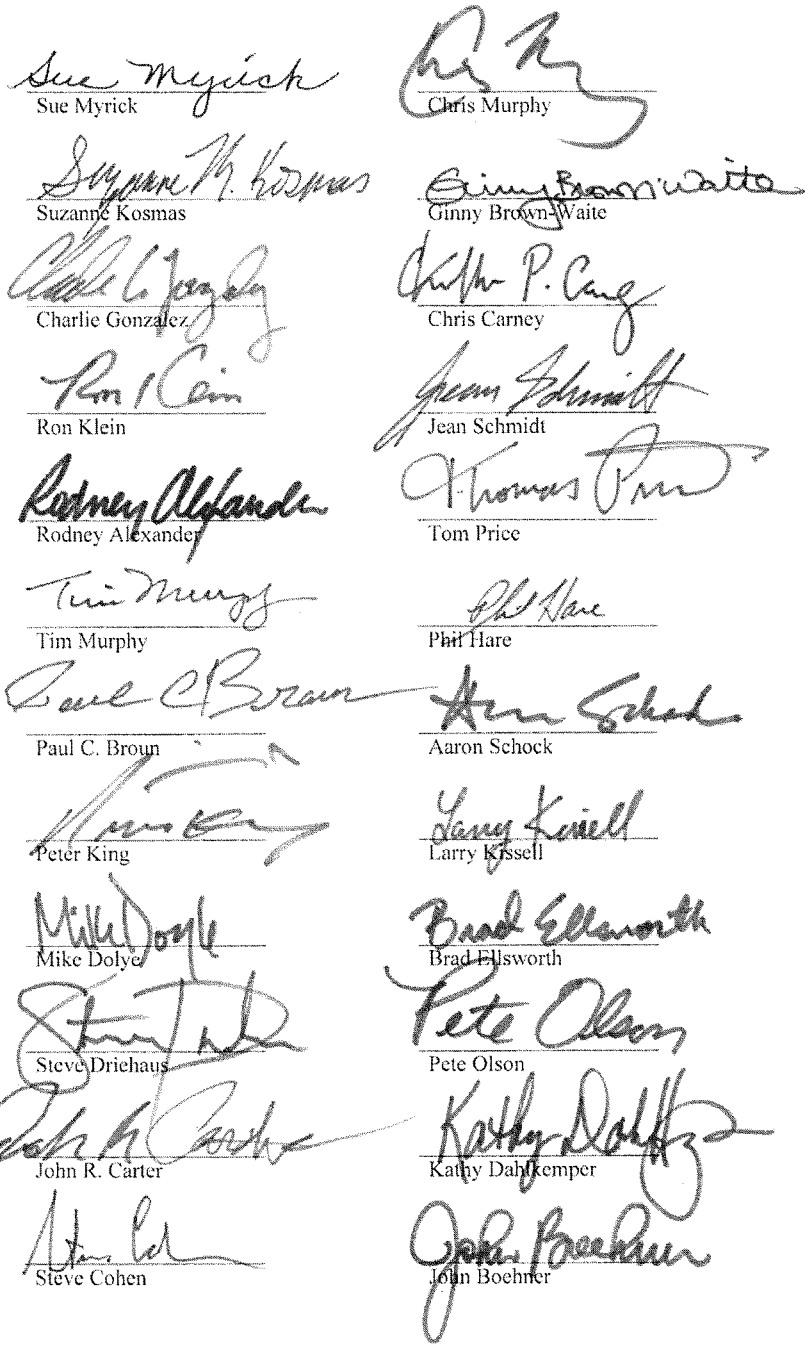
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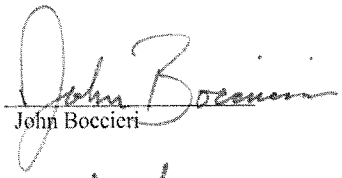
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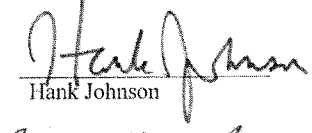
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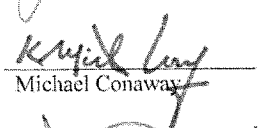
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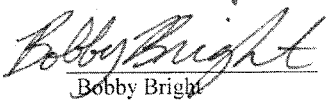
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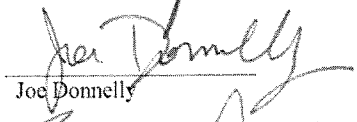
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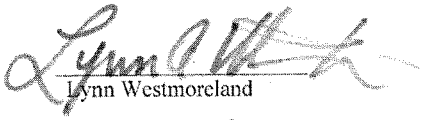
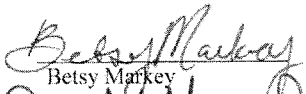
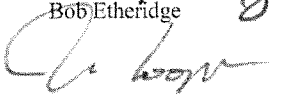

Lynn Westmoreland


Robert Latta


John Hall


Bob Etheridge


Betsy Markey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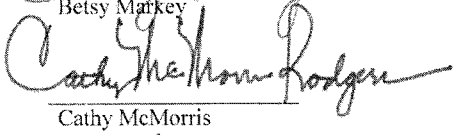
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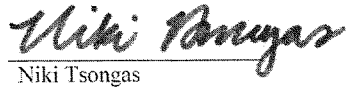
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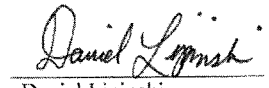
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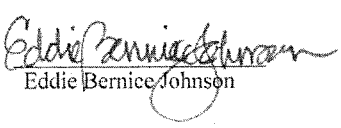
Eddie Bernice Johnson


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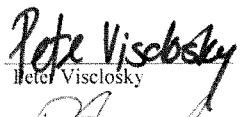
Ileana Ros-Lehtinen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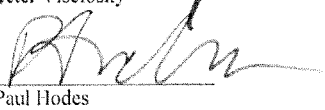
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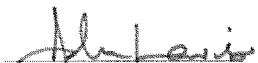
Heath Shuler


Mary Jo Kilroy


Robert J. Wittman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Zachary Space


Jim McDermott


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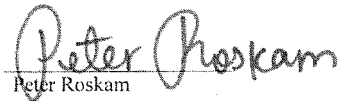
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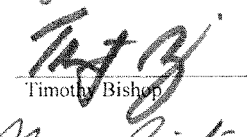
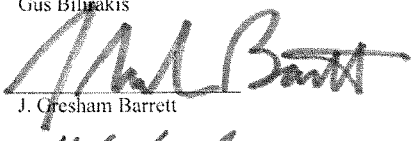
Danny K. Davis


Timothy Bishop


Leonard Boswell


Gus Bilirakis


Henry E. Brown, Jr.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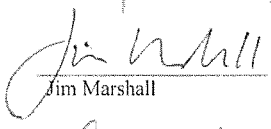
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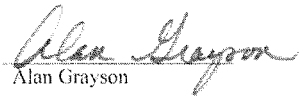
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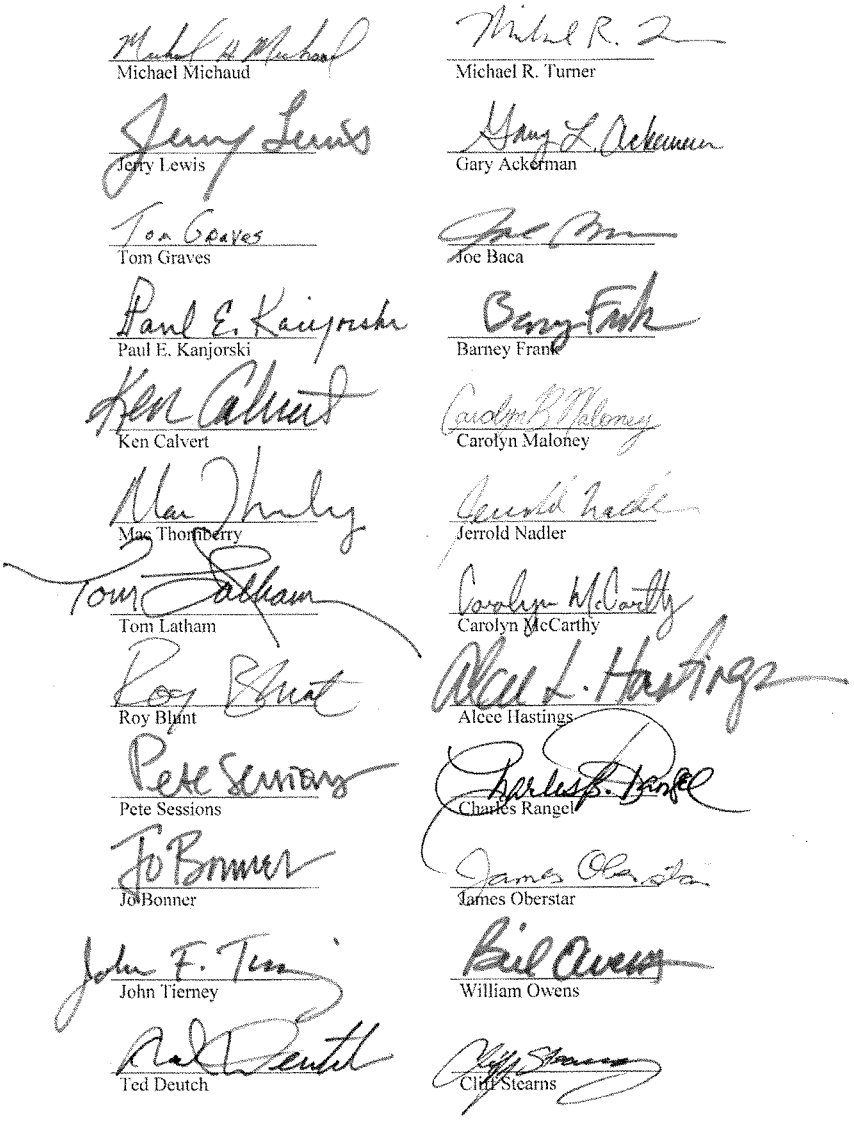
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Tom Latham
Carolyn McCarthy
Roy Blunt
Alcee Hastings
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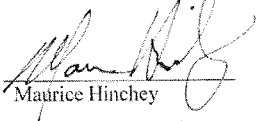
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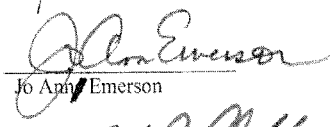
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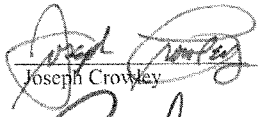
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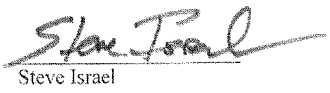
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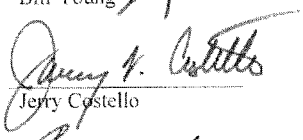
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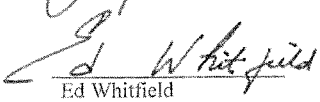
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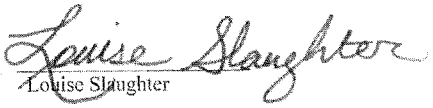
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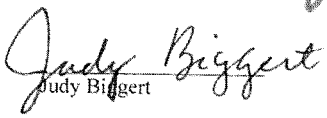
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Mark Steven Kirk


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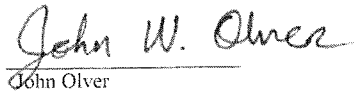
John Olver

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

AUG 3 0 2010

The Honorable Jason Altmire
U.S. House of Representatives
Washington, DC 20515

Dear Representative Altmire:

Thank you for your letter regarding the Medicare competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and your concerns about the program's ability to meet the medical needs of your constituents. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention and wants to assure you that we share your desire to provide high quality access to care for all Medicare beneficiaries.

In particular, we share your commitment to ensuring that qualified suppliers are selected to participate in the DMEPOS competitive bidding program. Having learned from our initial experience in 2008, we are working aggressively to improve operational processes for the program, address stakeholder concerns, and implement the changes required in the Medicare Improvements for Patients and Providers Act of 2008. To that end, we are dedicating extensive resources within CMS to implement the program in a transparent, orderly, and effective way. In addition, we have held numerous meetings with the Program Advisory and Oversight Committee (PAOC) soliciting their input on all aspects of the competitive bidding program.

The current Medicare fee-for-service DMEPOS benefit is plagued by an obsolete pricing methodology, grossly inflated prices, and a well-documented proliferation of fraud. The Department of Health and Human Services' Office of Inspector General, the Government Accountability Office, and other independent analysts have repeatedly highlighted that the prices paid by Medicare for certain DMEPOS items are excessive, sometimes three or four times retail prices and the amounts paid by commercial insurers. The inflated prices, in turn, increase the amount beneficiaries must pay out of pocket for these items.

The DMEPOS competitive bidding program is an essential tool to help CMS pay appropriately for health care—important not only to maintain Medicare beneficiaries' access to high quality medical products, but also to lower costs for beneficiaries and the Medicare program. The program provides proven value to consumers and taxpayers by lowering the cost of medical products, while ensuring consumer access to accredited suppliers that meet stringent quality and financial standards. It also strengthens protections against fraud. By establishing fair, market-based prices for DMEPOS, the competitive bidding program makes such items and supplies a less tempting target for abuse. In addition, contract suppliers will be closely monitored under the program, which reduces the ability of such suppliers to engage in fraudulent activity.

To ensure qualified suppliers are selected to participate in the DMEPOS competitive bidding program, CMS significantly increased our scrutiny of bidders on the front-end, instituting a number of critical improvements to the supplier selection process for the Round One Rebid. For example, we conducted an extremely rigorous and comprehensive verification of bidder compliance with licensure and accreditation requirements early in the bid evaluation process. In addition, we carefully scrutinized supplier capacity statements and expansion plans to verify that suppliers will be ready on day one to begin operating at the level reported in their bids. We included this more intensive review after consultation with members of the PAOC who had raised concerns about bidders entering a new area or product category. We also screened and evaluated all bids to ensure that they represent a rational and feasible payment for furnishing the item (i.e., that they are bona fide). In so doing, we verified that the supplier can furnish an item at the listed bid amount by reviewing additional information beyond that collected in 2008, such as supplier rationales that support documentation like manufacturer's invoices. We believe these process improvements that we have conducted and the intense scrutiny of bidders will result in a fair and effective supplier selection process, addressing the concerns raised following Round One about the need to ensure that suppliers serving Medicare beneficiaries under the program are appropriately qualified.

Another key part of CMS' efforts to implement the competitive bidding program in a transparent, orderly, and effective way is the timing of the announcement of the contract suppliers. While we agree that transparency is important and Congress and the public should have access to the list of final contract suppliers in a timely manner, we do not believe it would be appropriate or in the public interest to release any bidders' names before the contracting process is complete, as there are a number of risks associated with doing so.

First and foremost, we believe that providing a series of interim lists of suppliers would result in beneficiary confusion, undermining the orderly and effective implementation of the program. In addition, we have not yet notified the suppliers whose bids were not among the winning bids and we believe that these suppliers should be notified before the names of the suppliers with winning bids are released to the public. Further, announcing a subset of suppliers before the contracting process is complete could be viewed as giving those suppliers an unfair competitive advantage.

In addition, the premature release of information may jeopardize the procurement process itself. At the request of the DMEPOS industry, the Request for Bids, which outlined the requirements governing the bid submission and evaluation process, indicated that bidder information could only be disclosed in an anonymous or aggregate format and that proprietary information would be protected from disclosure. Further, standard procurement rules prohibit disclosing the identities of bidders until after contracts are final. Under the DMEPOS competitive bidding program, the contracting process is not complete and contracts are not awarded until CMS signs the contracts, and CMS does not sign the contracts until all of the contract suppliers have signed. Although this is a fairly time-consuming and labor-intensive process, we anticipate that the contracts will be signed by all parties by the end of September. CMS is committed to publicly sharing the list of final contract suppliers at that time. We would be happy to provide a detailed briefing to you and your staff when this announcement is made.

We appreciate your interest in ensuring that qualified suppliers are participating in the DMEPOS competitive bidding program and look forward to working with you to implement this important program and achieve our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the cosigners of your letter.

Sincerely,

Donald M. Berwick, M.D.

Testimony Before the Energy and Commerce Subcommittee on Health
"Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access"
The Honorable Ron Klein
September 15, 2010

I would like to thank this distinguished subcommittee, and in particular Chairman Pallone and Ranking Member Shimkus, for holding this important hearing and for allowing me to provide this testimony. Medicare's competitive bidding program for durable medical equipment and prosthetics, orthotics, and supplies (DME) remains a great concern for me and my South Florida constituents.

Although Congress previously mandated the competitive bidding program in the Medicare Modernization Act of 2003, I have seen firsthand the chaotic implementation of round 1 of the competitive bidding program during my two terms in Congress. I wrote to this committee along with eight of my freshman colleagues about our concerns that the bidding process was unclear, erratic, and unrealistic, and urged for a delay in implementation.

We were not alone in our criticisms. After committee hearings, the 110th Congress passed the Medicare Improvements for Patients and Providers Act (MIPAA), which postponed implementation of round 1 until 2009 and round 2 until 2011. To comply with Pay-Go rules, MIPAA also reduced payments for 2009 by 9.5%--a reduction that the DME industry agreed to in a good-faith effort to work with Congress to resolve these problems.

While my constituents in South Florida were relieved in the implementation's delay, MIPAA failed to address the underlying problem, which is the competitive bidding process itself. Let me be clear. I have no doubt that competitive bidding can work to reduce overpayments in Medicare and other federal programs. My great concern is that the competitive bidding process for DME is broken beyond repair.

First, the DME competitive bidding program contains strong incentives to game the system. By calculating the bid price based on the median winning bid, the DME competitive bidding program incentivizes bidders to undercut a bid because they are not bound by the bid price they submit. Instead, there is a reasonable expectation that any low-ball bid will be pulled up by the median bid price that all winning bidders will be paid. Therefore, irrational or irresponsible bids are unduly rewarded.

Second, the DME competitive bidding program encourages "predatory pricing," allowing larger out-of-state companies to force out local small businesses by undercutting their bids. It's very questionable whether these larger companies can provide the same level of service and care that a local company with a history in the community can.

Predatory pricing could also force smaller companies to submit bids that are either at or below the cost of these supplies. While these "suicide bids" may help small businesses survive in the short-term, these rates are not sustainable over the long-term and will force cuts in other areas. Other reputable small businesses will be driven out of business. One study found that up to 90

percent of DME companies could leave the Medicare program. Taken together, the cumulative result is to eliminate local jobs at a time when the economy is struggling to recover from the worst recession in our lifetimes.

In addition to local small businesses, I am concerned that the DME competitive bidding program could result in Medicare's most vulnerable beneficiaries experiencing medical complications as a result of inferior products or inadequate service that could send them to the emergency room, or worse, lose the freedom to live at home with dignity.

Healthcare is very personal to Americans. We want to know that our oxygen tank or our wheelchair that we are relying on for our very lives is going to work not just during the initial installation, but at three in the morning when our lives may be at stake. We owe it to our seniors who depend on these supplies to provide them with the best quality products at the most economic price possible, without sacrificing quality or care. The DME competitive bidding program is no way to treat our seniors, and it's no way to treat our local companies who are doing the right thing, following the law, and providing good paying jobs for our economy.

In conclusion, I urge this subcommittee to seriously question the efficacy of the DME competitive bidding program and join me in calling for its permanent repeal.

Thank you and I yield back my time.

JAMES R. LANGEVIN
2D DISTRICT, RHODE ISLAND

COMMITTEE ON ARMED SERVICES
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STRATEGIC FORCES

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COMMITTEE ON BUDGET

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September 13, 2010

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
Office of the Secretary
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius,

I am writing to request that you exclude adjustable wheelchair seating from the second round of the Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). As a quadriplegic who utilizes a wheelchair for my mobility needs, I have first-hand knowledge of how important it is to have access to a properly-fitted, adjustable skin protection seat cushion. Additionally, over twenty patient groups representing the disability community have joined in support of this request, including the Paralyzed Veterans of America.

I am concerned that the competitive bidding of adjustable skin protection seat cushions for those who spend long periods of time in wheelchairs will lead to reductions in the range of seating options and services offered by winning suppliers under the Competitive Bidding Program. This, in turn, will lead to a reduction in the quality of care and will very likely result in an increase in costly decubitus ulcers and other medical complications associated with long-term wheelchair use. Therefore, in limiting access to the appropriate adjustable skin protection seat cushion for wheelchair users, Medicare will not save money, but will instead spend more on costly medical care for wounds that could have been prevented.

Permanent wheelchair users spend many hours, day after day, in a seated position applying a large percentage of their body weight on a single portion of the body. This makes it all that more important that these individuals have access to the appropriate, adjustable skin protection seat cushions so the cushion can evenly distribute weight, reduce deformation, and improve posture while in a seated position. Proper seating helps to keep blood flowing and skin breakdowns to a minimum. Further, long-term wheelchair users' weight and shape will change over time. This reinforces the needs for adjustable seating so that the product can be readjusted over time as the individual's weight or shape change.

It is important that we find efficiencies in Medicare that reduce costs while protecting the quality of care that individuals with chronic, disabling conditions receive. In that vein, I request that you ensure beneficiary access to adjustable skin protection seat cushions by excluding them from Round 2 of the DMEPOS Competitive Bidding Program. I look forward to working with you on this matter as the competitive bidding process continues.

Sincerely,

Jim Langevin

Jim Langevin
Member of Congress

Cc: Chairman Henry Waxman, Committee on Energy and Commerce
Ranking Member Joe Barton, Committee on Energy and Commerce
Chairman Sander Levin, Committee on Ways and Means
Ranking Member Dave Camp, Committee on Ways and Means

Written Statement of the

DIABETES ACCESS TO CARE COALITION

Submitted to the

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

Regarding

MEDICARE'S COMPETITIVE BIDDING PROGRAM FOR DURABLE MEDICAL EQUIPMENT: IMPLICATIONS FOR QUALITY, COST, AND ACCESS

September 15, 2010

The Diabetes Access to Care Coalition (DACC) applauds the Subcommittee for holding this hearing at this crucial time before implementation of Medicare's Competitive Bidding Program (CBP) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), and for providing a venue to hear both support for and concerns about the program from stakeholders.

The DACC is a coalition of patient advocates, providers, suppliers, and manufacturers of diabetes testing supplies that is committed to ensuring that Medicare beneficiaries with diabetes mellitus maintain access to high quality products and services through avenues of their choice in order to monitor their blood glucose levels and avoid complications stemming from diabetes. In light of this mission, the DACC has a strong interest in the Medicare CBP and its potential implications for Medicare beneficiaries.

The DACC supports the goals of the Competitive Bidding Program (CBP) to determine appropriate payment for durable medical equipment and supplies and promote program integrity. The DACC is committed to working with Congress and the Centers for Medicare and Medicaid Services (CMS) to ensure implementation of the CBP in a manner that achieves these goals while protecting beneficiary access to necessary items and services.

Importance of Self-Monitoring of Blood Glucose

Nearly one in five Medicare beneficiaries, more than 9 million elderly Americans, has diabetes.[1] For many of these beneficiaries, effective and consistent self-monitoring of blood glucose levels is essential to diabetes control. Increased risk of devastating and costly complications – such as blindness, kidney damage, cardiovascular disease, and lower-limb amputations – are associated with inadequate glucose control. Experts consider glucose self-monitoring such an important tool in diabetes management, that increasing the proportion of persons with diabetes who self-monitor is a national public health objective under the Center for Disease Control and Prevention's (CDC's) Healthy People 2010. For these reasons, the DACC has long been concerned that, if beneficiary access to the most appropriate or familiar self glucose-monitoring systems is disrupted, patient compliance with treatment regimens may be jeopardized and health outcomes could be adversely impacted.

Incentives Created by CBP May Limit Beneficiary Access

On January 1, 2011, CMS will implement Round 1 of the CBP for certain items of durable medical equipment and supplies, including diabetes testing supplies, such as blood glucose testing strips, purchased through mail order. A fundamental premise of the CBP is that it will save costs for Medicare and its beneficiaries because prospective suppliers are not only required to submit bids that are below current Medicare reimbursement amounts, but also have powerful incentives to submit bids that are substantially below current Medicare reimbursement amounts. While cost-reduction is a desirable outcome, this requirement also incentivizes prospective suppliers to limit the range of product offerings and furnish only the lowest cost versions of

[1] CMS, Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses, Medicare Fact Sheet, cited in Health Policy R and 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 D.C., January 2006), p. 9.

products. In the case of diabetes testing supplies, this incentive is expected to result in suppliers carrying a very limited number of brands of diabetes testing strips, leading suppliers to pressure beneficiaries to switch to a blood glucose meter that is compatible with one of the brands of testing strips carried by the supplier.

Physicians and other health care practitioners prescribe testing systems on the basis of medical necessity, the needs of individual patients, and their experiences with the reliability and performance of specific products. For example, some beneficiaries need audible reading or large displays because of poor vision. Beneficiaries who are physically challenged or have dexterity issues, perhaps because of paralysis arising from stroke, may need to be able to operate a meter and handle strips with one hand. For these and other reasons, physicians often prescribe, and patients often choose, particular meters for important clinical reasons.

Testing systems are not interchangeable. Each system (manufacturer and model) is comprised of a meter and corresponding strips. Brand "A's" meter functions only with Brand "A's" strips. Brand "X" strips will not work in Brand "A" meters. As such, if a beneficiary is using a Brand "A" testing system, but the contracted supplier does not carry Brand "A" strips, then one of three things will happen:

- The supplier will attempt to obtain the Brand "A" strips for the beneficiary (in instances where the physician actually prescribes and documents that a particular testing system is medically necessary to avoid an adverse event with a different system, the contract supplier will be required to either furnish the item, consult with the physician about a suitable substitute, or make arrangements for the beneficiary to obtain the item elsewhere);

- The supplier will attempt to persuade the beneficiary to switch to a different testing system; or

- The supplier will advise the beneficiary that it cannot complete the order, and the beneficiary will have to seek replacement strips, compatible with their current meter, elsewhere.

Under each option, beneficiary access to testing strips will be compromised. Medicare paid for more than 1 billion strips in 2009.[2] If a contract supplier in a competitive bid area has not made arrangements with the manufacturer of Brand "A" strips to obtain large volumes (*e.g.*, 25 million strips), the supplier is not going to be able to fulfill demand for Brand "A" strips by attempting to obtain the strips on an *ad hoc* basis when orders for those strips begin to come in on January 1st. If the supplier concedes that it is unable to furnish Brand "A" strips, then the beneficiary will be left to seek the strips elsewhere. However, the most likely scenario is that the supplier will instead attempt to persuade the beneficiary to switch testing systems to a brand of strips that the supplier does carry. If a beneficiary agrees to switch testing systems, they will need training to learn how to use the new system correctly—each system has unique directions for use. For

[2] Source: IMS Xponent PlanTrak database for US market, Medicare Rx subset covering period April 2009-March 2010.

many beneficiaries, switching to an unfamiliar system will be a burden and cause substantial anxiety. As a result, beneficiaries may decide not to test their blood sugar as prescribed, which could lead to poorer health outcomes.

CMS Solution – "Anti-Switching Rule"

CMS has recognized the importance of ensuring that beneficiaries have access to testing strips that are the most clinically appropriate and compatible with the meters prescribed by their physicians or selected by the beneficiary, and that these beneficiaries are protected from the influence of suppliers who have powerful incentives under competitive bidding to persuade beneficiaries to switch to the lowest cost testing systems. To that end, CMS has proposed an "Anti-Switching Rule" that would require suppliers to furnish the brand of diabetes testing supplies that works with the blood glucose monitor selected by the beneficiary and clinician, and that would prohibit the supplier from influencing or incentivizing the beneficiary to switch from their current brand of monitor and testing supplies. The DACC agrees with CMS that this Anti-Switching Rule is an essential beneficiary protection and necessary component to a viable CBP for diabetes testing supplies.

However, CMS has not proposed to apply the Anti-Switching Rule to Round 1 of the CBP. CMS has proposed to implement the Anti-Switching Rule only in subsequent rounds of the CBP. Thus, a beneficiary protection that CMS presently considers to be necessary will not, in fact, protect the beneficiaries in the 9 areas that will be subject to the CBP when it begins on January 1, 2011. In other words, a beneficiary protection that CMS deems vital for beneficiaries in Tampa will not protect beneficiaries in Ft. Lauderdale, Miami or Orlando. While beneficiaries in Philadelphia may be protected, those in Pittsburgh will not be.

Without the protections afforded by the Anti-Switching Rule, beginning January 1, 2011, Medicare beneficiaries with diabetes who obtain their testing supplies through a CBP supplier will be at significant risk of undue influence in their choice of supplies.

Medicare has an important protection in place where a physician prescribes a specific testing system. In instances where the beneficiary's physician prescribes and documents the medical need for a particular testing system, the contract supplier will be required to either furnish the item, consult with the physician about a suitable substitute, or make arrangements for the beneficiary to obtain the item elsewhere. However, this protection only applies to instances where a physician prescribes a specific testing system because the physician has determined that an adverse medical outcome is likely to occur if the beneficiary does not receive the specific system. It does not protect the much more common instance where the physician and beneficiary together have selected and grown accustomed to a testing system for reasons that are particular to the beneficiary—unrelated to risk of adverse medical outcome.

Many beneficiaries could switch testing systems without an adverse medical outcome. However, testing systems are often complicated and difficult to learn, especially for the elderly for whom changes in routine can be traumatic. For these beneficiaries, changes to routines and the need to learn how to properly use a different testing system could lead the beneficiary to test less often or inaccurately. In either case, the beneficiary's testing regimen is compromised, and the risk of complications arising from diabetes may increase.

Of course, beneficiaries who cannot obtain their testing supplies through mail order suppliers can always turn to retail settings, which are presently exempt from the CBP, and which will continue to stock a wide variety of testing systems. For this reason, the DACC has urged CMS to continue to exempt retail settings from the CBP, so that retail pharmacies remain as a necessary safety valve, ensuring that beneficiaries will have immediate access to the specific diabetes testing supplies they need should mail order suppliers limit supply options or be unable to fulfill demand for certain products. However, relying on retail pharmacies to fulfill demand is not a complete solution. There are many reasons why beneficiaries use mail order suppliers. For many, it is a matter of necessity, because they are unable to access a retail setting as a result of diminished mobility. For these beneficiaries, it is essential that mail order suppliers be able to furnish their chosen brand of testing supplies. For these beneficiaries especially, an Anti-Switching Rule is necessary.

The Anti-Switching Rule can be implemented during Round 1 without necessarily delaying the implementation of the CBP on January 1, 2011—if CMS acts quickly. If the bidding suppliers intend to furnish the brands/models that beneficiaries currently receive, then the Anti-Switching Rule will pose no incremental burden or cost for those suppliers. Only those suppliers who have no plans or intentions to furnish the brands/models that beneficiaries currently receive would be burdened by the Anti-Switching Rule. For those suppliers that do not intend to furnish the brands/models beneficiaries currently receive, CMS could time the implementation of the Anti-Switching Rule to allow the program to be implemented on January 1 while giving suppliers time to submit revised bids, if necessary. As long as new bids do not exceed CMS's requirements for savings under the program, these contracts could be reformed to accommodate the new rule. If new bids exceed savings requirements, the suppliers could be given the choice either to comply with the Anti-Switching Rule or to withdraw from the CBP.

Recommendation

Because the Anti-Switching Rule is an essential beneficiary protection, DACC urges Congress to require CMS to apply the Anti-Switching Rule to Round 1 of the CBP before Medicare beneficiaries are subject to the new program.

Additional Written Questions for the Record
Laurence Wilson's Hearing
"Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access"
Before
House Energy & Commerce Health Subcommittee

September 15, 2010

Responses to the Honorable Mike Doyle

1. **What steps has CMS taken to ensure that contract suppliers will be able to furnish the diabetes testing supplies currently used by beneficiaries in the competitive bidding area?**

Answer: CMS has contracted with suppliers to meet the demand for mail order of a wide variety of brands of diabetic testing supplies in the Round 1 Rebid areas. Beneficiaries will have access to all of the top selling brands of diabetic testing supplies in the nine competitively bid areas. If CMS determines that additional suppliers are needed under the Round 1 Rebid to ensure access to particular brands of diabetic testing supplies that are necessary for beneficiary-owned glucose monitors, additional mail-order diabetic supply contracts can be added.

Suppliers under the DMEPOS competitive bidding program must comply with the physician authorization process and all other terms of their contracts, including the nondiscrimination requirement. Under the physician authorization process, if a physician or treating practitioner prescribes a particular brand of item and documents in the beneficiary's medical record the reason why the particular brand is needed in order to avoid an adverse medical outcome, the contract supplier must furnish the prescribed brand, consult with the physician to find an appropriate alternative brand, or work with another contract supplier to furnish the prescribed brand. The nondiscrimination term of the contract requires that the brands of items made available by the contract supplier under a competitive bidding program must be the same brands of items that the supplier makes available to other customers. Failure to comply with the physician authorization process, the non-discrimination requirement, or any other terms of the competitive bidding contract constitutes a breach of contract and can result in termination of a supplier's contract.

For the national mail order program and all future competitions for diabetic test strips, additional protections will be in place to further ensure access to a wide range of products, both before and after contracts are awarded. The statute requires that before a contract is awarded under a future competition for diabetic test strips, the bidding supplier must demonstrate that its bid covers at least 50 percent of available types of test strip products. In addition, suppliers awarded contracts for furnishing diabetic test strips in the future will be required to meet a new "anti-switching" contract term recently established in our regulations that prohibits suppliers from influencing or incentivizing beneficiaries to switch from the brand of test strips they are currently using to another brand of test strips.

2. If a contract supplier does not offer the particular brand of diabetes testing strips sought by a beneficiary, what options are available to the beneficiary to obtain those specific replacement strips?

Answer: CMS is confident that Medicare beneficiaries will be able to obtain the top selling brands and many other brands of test strips from suppliers awarded contracts under the competitive bidding program.

In the event that a beneficiary is not able to obtain a particular brand of test strips through the national mail order program, the beneficiary has the option to purchase test strips from any enrolled supplier able to furnish that brand on a non-mail order basis. This area of the program will be monitored closely to determine if additional steps are necessary to ensure beneficiaries' access to diabetic testing supplies in the 9 Round 1 Rebid areas.

3. What anticipated problems does the recently proposed Anti-Switching Rule seek to address or avoid?

Answer: The "anti-switching" contract term was added to our regulations, in conjunction with the special "50 percent" rule mandated by section 1847(b)(10)(A) of the Social Security Act, to enhance beneficiary access to particular brands of diabetic testing supplies in future competitions for diabetic testing supplies. The rule has been added through notice and comment rulemaking after careful consideration of comments and at the advice of members of the public who have expressed concern about this issue. CMS is clear that beneficiaries cannot now or in the future be compelled to switch monitors by a supplier. The rule is designed to prevent suppliers from actively influencing or incentivizing beneficiaries from switching products. CMS is aware that many suppliers currently offer free glucose monitors, cookbooks, and other incentives to beneficiaries to encourage them to switch from the brand of test strips they are currently using to another brand of test strips, and we want to be sure that these practices do not result in denied access to diabetic testing supplies.

4. If the recently proposed Anti-Switching Rule is important to address perceived shortcomings in the competitive bidding program, why is it not important to have this rule in the 9 areas where the competitive bidding program will be implemented on January 1, 2011?

Answer: The anti-switching rule prohibits suppliers from influencing or offering incentives to entice beneficiaries to switch from the brand of test strips they are currently using to another brand of test strips. While we do not believe that these common marketing tactics are resulting in any problems of beneficiary access at the present time, due to Congressional and stakeholder concerns, we are adding this requirement in the future to preserve access to a wide variety of brands in the future rather than to address specific problems with access to brands. This anti-switching rule will be a component of Round 2 of competitive bidding and is currently a part of the Round 2 notice and comment rulemaking.

5. What other protections might protect beneficiaries against the situations that would be addressed by the Anti-Switching Rule?

Answer: Beneficiaries cannot now or in the future be compelled to switch monitors by a supplier. Nonetheless, Medicare suppliers do employ switching tactics to encourage beneficiaries to switch brands. Despite this fact, we believe that physicians and beneficiaries are able to obtain the brands of test strips they prefer to use today. The "50 percent rule" and the "anti-switching rule" will serve to enhance access to a wide variety of products under future national competitions, but these rules are not intended to correct any current abuse or in and of themselves necessary to ensure access to diabetic testing supplies under the DMEPOS competitive bidding program. Although we believe that suppliers and physicians have access to the brands of diabetic supplies in the Round 1 Rebid areas that they prefer to use, we will monitor the programs and contract suppliers closely in these areas.

6. Can CMS explain why the program for the Round One Rebid is going to be successful at 32 percent touted savings when the Original Round One had to be stopped after 14 days with 26 percent purported savings?

Answer: The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) mandated the Round 1 Rebid in conjunction with a temporary delay of the program and limited program refinements. In implementing the Round 1 Rebid, CMS has incorporated all of the program improvements required by MIPPA. In addition, CMS implemented a number of other important improvements based on our evaluation of the 2008 bidding process, feedback from stakeholders, and advice the Program Advisory and Oversight Committee (PAOC) received through two public meetings and three conference calls. Some examples of these key operational improvements include an upgraded bidder education program completed prior to the opening of the bid window, a new and improved online bidding system, enhanced bid evaluation processes such as a comprehensive upfront licensing verification process, a bona fide bid evaluation process, and increased scrutiny of expansion plans for suppliers new to an area or product category. All of these changes for the Round 1 Rebid resulted in better compliance, more bidders, improved bids, and projected savings of 32 percent over 10 years, as compared to the original Round 1 process which yielded 26 percent savings.

7. Your testimony indicates that you have improved the provider screening process. Can you explain how?

Answer: We improved the screening process in three significant areas: licensure review; bona fide bid review; and capacity analysis:

Licensure Review: CMS only offered contracts to suppliers that were properly licensed in each State and for each particular service that the suppliers applied for at the time of their bid application. In the initial Round 1, bidders were also required to meet all State licensure requirements prior to submitting a bid. However, there were concerns that some of the 2008 contract suppliers did not have all required State licenses. To alleviate these concerns in the Round 1 Rebid, CMS conducted a rigorous, comprehensive verification of bidder's compliance with all applicable State licensure requirements early in the bid evaluation process. This involved checking supplier licenses already on file with Medicare, working directly with States to confirm the licensure status of specific bidders, and working directly with suppliers when necessary to verify that they meet the licensure requirements.

Bona Fide Bids: Under the DMEPOS competitive bidding program, only suppliers that submitted "bona fide" bids may be awarded contracts. Accordingly, all bids submitted were screened to ensure that they represent a rational, sustainable, and feasible payment for furnishing the item. In instances where a bid was identified through the bona fide bid screening process as extremely low in relation to other bids, CMS further evaluated that bid to confirm that the supplier could furnish the item at the listed bid amount. In so doing, CMS reviewed additional information beyond that collected in 2008, such as supplier rationales that support documentation like manufacturer's invoices. Suppliers that submitted bids that were not found to be "bona fide" after review of certain information were not awarded contracts for the applicable product category and CBAs; only bona fide bids were included in the calculation of the single payment amounts.

Capacity and Expansion Plans: CMS improved its capacity and expansion plan review for the Round 1 Rebid after consultation with the PAOC. The PAOC raised initial concerns that bidders new to an area or product category or reporting high capacity figures might not be able to ramp up to their reported capacity in time to meet the projected demand at the beginning of the contract period.

To address these concerns, CMS utilized a "capacity ramp up" analysis to review what percentage of demand in 2011 would be met by experienced suppliers reporting no expansion or a modest expansion in capacity and what percentage of demand in 2011 would be met by new suppliers or experienced suppliers reporting more than a modest expansion in capacity. In any case where this second category of suppliers was counted on to meet any portion of projected demand in 2011, the expansion plans of these suppliers were scrutinized with particular emphasis on liquid assets and available credit needed to expand their capacity. If this information did not substantiate the supplier's estimated capacity, CMS adjusted the capacity of the supplier to the supplier's historic level for the purpose of selecting enough contract suppliers to meet expected demand. This capacity analysis had no impact on whether or not a contract was awarded and was limited to an analysis of what supplier capacity could be justified. Further, as in the initial Round 1, in order to ensure appropriate capacity planning and market competition between DMEPOS suppliers in each area, CMS did not allow any one supplier to account for more than 20 percent of the market. Finally, it is important to note that CMS' projected demand calculations for rented items of durable medical equipment (DME) in 2011 was not discounted in any way even though we predict that a large number of these items will be furnished by non-contract, grandfathered suppliers. In order to ensure sufficient capacity to serve all beneficiary needs, contract supplier capacity was reviewed as if 100 percent of demand must be met by the winning suppliers.

8. Round 1 in 9 areas is scheduled to begin January 1, 2011; CMS plans to begin the bid submission process in the Spring of 2011. How will CMS have time to assess the impact of Round 1 to make changes to Round 2 of the bid program?

Answer: CMS is already learning from the Round 1 Rebid and has strong tools in place to monitor and evaluate the program when it begins in January. By the end of Spring 2011, CMS will have several months of data on the Competitive Bidding Program. CMS intends to begin the bidding process for Round 2 in Spring 2011.

9. **Can you explain how you will ensure beneficiary access to the specific make/model goods that they need, especially in under-defined codes like diabetic supplies and wheelchair accessories? Based on the rates you've announced it would appear that certain make/model products would have to be sold at a loss in order to be provided at the winning bid rate. Did you factor in general and administrative overhead costs into your calculations in addition to simply evaluating invoices when considering bids?**

Answer: We do not view the current codes for diabetic supplies and wheelchair accessories as "under-defined". In addition, there is ample evidence based on the Department of Health and Human Services Office of Inspector General (OIG), Government Accountability Office (GAO) reports, and retail internet information that current Medicare fees are excessive. For example, the OIG found in 2006 that Medicare would allow $7,215 in payments over 36 months to oxygen suppliers for oxygen concentrators that cost $587, on average, to purchase. In 2009 the OIG found that in 2007 Medicare allowed $4,018 for standard power wheelchairs that cost suppliers $1,048 to acquire.

In order to retain their status as enrolled Medicare DMEPOS suppliers, all suppliers are required to be accredited and meet standards that ensure access to quality items and services. In addition, contract suppliers will be closely monitored to ensure that they meet additional standards that other DMEPOS suppliers are not currently required to meet such as the physician authorization and nondiscrimination requirements. Contract suppliers that do not furnish quality items and services in accordance with the terms of the contract may have their contract terminated and/or supplier number and billing privileges revoked.

Suppliers that submitted low bids were required to furnish information to verify that their bids were feasible and bona fide. This included a written rationale in support of their bid amounts and additional documents such as supplier invoices and purchase orders or agreements. This information was reviewed by CMS to ensure that the bids were rational and feasible. If a supplier did not provide information to verify that a bid was bona fide, or the information submitted did not support the bid amount, the supplier was eliminated from competition for the applicable product category and CBA.

10. **What happens if competitive bidding fails in the first several months? Do you have a backup plan? I would also like to know what CMS' definition of failure? How will CMS assess whether the program is successful since surely just a price reduction can't measure whether beneficiaries are being negatively impacted?**

Answer: While the projected savings to Medicare are an important part of DMEPOS competitive bidding, the success of the competitive bidding program hinges on beneficiary access to quality items and services. To that end, CMS has ensured that access to care for beneficiaries will be ample in several ways. First, we selected enough suppliers to meet the beneficiary demand throughout the contract period, starting on day one. The methodology we used to calculate future demand was designed to ensure that there are sufficient suppliers for each area. Contracts were awarded to a significant number of suppliers already furnishing the product category in the areas for which they were awarded contracts. If these suppliers do not maintain quality service, they may have their contracts terminated. We note that over 90% of suppliers offered a contract accepted the contract, indicating that suppliers are eager to be a part

of this program at the payment amounts set through the competitive bidding process. Finally, the grandfathering policy allows suppliers not offered contracts to continue to furnish oxygen and oxygen equipment and rented DME to beneficiaries receiving the equipment on January 1, 2011. We expect that a high percentage of non-contract suppliers furnishing items that can be grandfathered will choose to become grandfathered suppliers.

CMS will be actively monitoring program implementation and will be prepared to address any issues that may arise. CMS will be seeking feedback from beneficiaries through consumer satisfaction surveys conducted before and after the implementation of the program. CMS will provide a local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen, who will closely monitor transition activities, conduct a local assessment of supplier activities, analyze trends, and identify and address any emerging issues. There will also be an inquiry and complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues. In addition, contract suppliers are responsible for submitting quarterly reports identifying the brands of products they furnish, which will be used to inform beneficiaries and caregivers and help CMS evaluate supplier compliance to certain contract terms. CMS will also conduct claims analysis to identify utilization trends, monitor beneficiary access, address aberrancies in services, and target potential fraud and abuse. Finally, CMS has appointed a Competitive Acquisition Ombudsman who will respond to complaints and inquiries from beneficiaries and suppliers about the application of the program and will issue an annual Report to Congress.

11. The bid ranges are important to validate the accuracy/validity of the bids. How many bids were eliminated because of low or unrealistic fees? How many bids and suppliers were disqualified in total?

Answer: The DMEPOS competitive bidding program final rule requires that each bidder submit a bona fide bid as specified in the request for bids. In other words, each bid amount must be a rational, feasible, and sustainable payment for furnishing the item. If a supplier submitted a non-bona fide bid for a single item in a product category, then the supplier was eliminated from competition for that product category.

A total of 102 out of 6,215 bids (1.64%) were excluded as being non-bona fide bid amounts. A total of 4,891 bids and 638 suppliers were not successful; most of these suppliers were not successful because their bids were above the winning range.

12. Have there been any studies to show that with a change in pricing of this magnitude that quality of products and service can be maintained? Business will not be able to continue the service level. Even when you look at lean management processes you do not see this type of savings in a business. Do we have any of those numbers for comparison?

Answer:
Competitive bidding for DMEPOS was proven effective in successful competitive bidding demonstrations in Polk County, Florida and San Antonio, Texas between 1999 and 2002. The

demonstrations, mandated by the Balanced Budget Act of 1997 (BBA), resulted in 20 percent savings for Medicare and beneficiaries and unchanged access to equipment and quality for beneficiaries. In addition, beneficiaries had overall high satisfaction with the service from these competitive bidding demonstration suppliers.

In addition, the Medicare program has a history of incrementally cutting inflated fee schedule amounts in an attempt to reduce them to reasonable levels. For example, oxygen and oxygen equipment is the largest DMEPOS category in terms of expenditures; several price reductions have been legislated by Congress over the past 23 years, and in each instance, the reduction in payment did not impact the quality of items furnished. Suppliers of oxygen concentrators and other stationary oxygen equipment received $313 per month on average or over $3,700 per year in 1997 for furnishing this equipment. The BBA mandated a 25 percent reduction in the Medicare allowed payment amounts for oxygen and oxygen equipment in 1998 and an additional 5 percent reduction in the Medicare allowed payment amounts for oxygen and oxygen equipment in 1999. As reported by the Government Accountability Office, this combined 30 percent reduction did not significantly impact access to quality items and services. The payment amounts for oxygen and oxygen equipment were further reduced by approximately 10 percent in 2005 by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and again by 9.5 percent in 2009 by MIPPA. Neither of these reductions significantly impacted access to quality items and services. After all of these reductions, suppliers of oxygen concentrators and other stationary oxygen equipment still receive approximately $175 per month or over $2,000 per year for up to three years for furnishing this equipment, which suppliers can purchase for about $600. The bids submitted by actual suppliers under the most recent round of competition under the program will help reduce payments for oxygen and oxygen equipment and other Round 1 items and services to a more appropriate level, which is the main goal of the program. The contract suppliers that submitted these bids and accepted contracts based on these bids will be closely monitored to ensure that access to quality items and services in the 9 Round 1 Rebid areas is preserved.

13. CMS is surveying consumers regarding the level of service and quality of care changes. What happens if there is an identification of change in quality and service? Is there a percentage change that will trigger some event by CMS? Aren't you concerned that your analysis of Round 1 will not be complete before CMS expands the program to an additional 91 areas in Round2?

Answer: In the demonstration areas of Polk County, Florida and San Antonio, Texas, surveys of participating beneficiaries showed that users of oxygen and other medical equipment were highly satisfied with their suppliers both prior to implementation of the demonstration and in the year after implementation.

We have made substantial improvements to the program since its delay in 2008. For example, our bidder education program and improved on-line bid submission system worked very smoothly. We were very pleased with results of these improvements and believe they can be easily adapted to include more areas. As noted above in the response to question 10, CMS has a

comprehensive monitoring plan in place and is prepared to address any issues that may arise. If there are any negative changes, we will address them as they are identified by our real-time monitoring program.

CMS is committed to beginning the Round 2 competition in 2011 as mandated by law. We are confident that we have the infrastructure in place for a successful Round 2.

14. How many DME providers that were initially offered contracts chose not to sign contracts? This is important because CMS calculates the bid price based on the group of initial offerees, not the group of providers that eventually sign contracts. This results in an artificially low bid price and contract suppliers that are less likely to be financially viable over the three-year contract period.

Answer: Ninety-two percent (92%) of suppliers offered contracts accepted those contracts.

15. How did CMS measure the credit-worthiness and financial viability of DME providers that submitted bids? What specific changes in its analysis of bidders has CMS made to ensure that contractors will be financially viable for the three year contract period? Who at CMS or your contractor actually reviewed financial statements and what was their expertise with home medical equipment service providers?

Answer: The competitive bidding law and regulations specify that CMS may not award a competitive bidding program contract to a supplier unless that supplier meets applicable financial standards. Applying financial standards to suppliers is needed to assess the expected quality of suppliers, estimate the total potential capacity of selected suppliers, and ensure that selected suppliers are able to continue to serve market demand for the duration of their contracts. The request for bids (RFB) specifies the financial information that we use to evaluate a supplier's financial health. We use the required tax and financial documents to calculate standard accounting ratios for each bidder.

The following financial ratios were used for the Round 1 Rebid: current ratio; collection period; accounts payable to sales; quick ratio; current liabilities to net worth; return on sales; sales to inventory; working capital; quality of earnings; and operating cash flow to sales. These ratios and the credit report and score were weighted and combined to determine a financial score. CMS also ensured that contract suppliers are able to meet demand for items and services by conducting a "capacity ramp up" analysis as outlined in the response to question 7 above. This step focused on new suppliers and suppliers planning to expand the number of items furnished under the program

The financial scores were evaluated by a team led by certified public accountants and home medical service experts at Palmetto GBA, and as with the entire bid evaluation process, was closely supervised by CMS.

16. Is CMS monitoring whether beneficiaries in the bid areas will be able to access the same brand products and level of services, particularly for beneficiaries with chronic conditions and needs?

Answer: CMS will be monitoring utilization very closely to see how it compares to utilization prior to implementation of the Competitive Bidding Program. In addition to our real-time monitoring, suppliers are contractually required to submit a quarterly report that indicates the manufacturer, model name, and model number for the items furnished to Medicare beneficiaries during the previous quarter. These reports will be monitored and compared to prior reports. Any notable changes in product availability will be investigated.

The Honorable Mike Rogers

1. **Earlier this year, CMS released a proposed rule that would give beneficiaries the choice of obtaining their diabetic testing supplies from any local pharmacy. However, I understand mail order prices for diabetes testing supplies will also be applied to retail pharmacy prices in future rounds beginning in 2016 of the competitive bidding program. Because it would be difficult for bricks and mortar pharmacies to accept mail order prices (which are often less than half of their current prices) do you have concerns about the potential lack of access for patients, particularly those in rural areas and seniors?**

Answer: In accordance with the provisions of the statute, competitive bidding programs are to be implemented throughout the United States for the purpose of awarding contracts for furnishing diabetic testing supplies. We have elected to use the authority provided in the statute by first phasing in mail order diabetic testing supplies as these are high volume items relative to diabetic testing supplies furnished on a non-mail order basis. While CMS has not yet determined how to implement these provisions of law with respect to non-mail order diabetic supplies, the statute allows several scenarios. Under one scenario, competitive bidding programs for non-mail order diabetic testing supplies would be phased in after the national mail order program has been implemented. This scenario would require that local pharmacies compete for contracts for furnishing non-mail order diabetic testing supplies throughout the United States. As an alternative, the payment amounts for non-mail order diabetic testing supplies could be adjusted using authorities provided by the statute, negating the need to phase in competitive bidding programs for these items and the need for local suppliers to bid for non-mail order supplies.

CMS appreciates your interest in this issue; any proposed methodology for establishing payment limits for non-mail order diabetic testing supplies in lieu of implementing competitive bidding programs for these items will be implemented through notice and comment rulemaking. All comments will be reviewed and evaluated on every issue, including access to items in rural areas.

2. **In the first round of competitive bidding, community pharmacies held only 2% of the winning bids, yet they hold one half of all active Part B supplier numbers. This seems to indicate that a very large supplier of Part B supplies will cease to provide those supplies under competitive bidding. How can CMS be sure that beneficiaries will continue to have access to their supplies, if all of these suppliers drop out of the program? What is CMS's response to concerns that beneficiaries in rural areas may**

have to travel long distances to receive their supplies once the number of suppliers is reduced under competitive bidding?

Answer: This assumption is incorrect. Community pharmacies that furnish non-mail order diabetic testing supplies were not required to compete under the Round 1 Rebid competitive bidding program and will not be required to compete under the national mail order program. Beneficiaries who choose to obtain their diabetic testing supplies on a mail order basis in the Round 1 Rebid areas will have access to these items from a supplier awarded a contract for furnishing mail order diabetic testing supplies. Any beneficiary in a Round 1 Rebid area who elects to obtain his or her diabetic testing supplies on a non-mail order basis may use a local community pharmacy enrolled with Medicare or any other enrolled supplier of non-mail order diabetic testing supplies.

When competitive bidding programs are established in the future for non-mail order diabetic testing supplies, or, alternatively, price limits for non-mail order diabetic testing supplies are established and implemented in the future in lieu of such competitions, we intend to implement these programs or price limits in a way that preserves access to diabetic testing supplies in all communities throughout the United States.

3. **In CMS's recent proposed rule regarding the Part B program for 2011, CMS recognizes the important role that pharmacists play in terms of face-to-face counseling and consulting with patients regarding Part B supplies and managing their illnesses, such as diabetes management. Because of the counseling role of pharmacists, patients who receive such face-to-face interactions are more likely to: take their medicines on-time; take them properly; refill meds before they run out; and avoid harmful drug interactions. What action is CMS taking to make sure that patients continue to receive such benefits if pharmacists drop out of the Part B program under competitive bidding? What is CMS's position and/or response to concerns that if pharmacists drop out of the Part B program, patients' loss of face-to-face counseling will negatively impact management of their illnesses and lead to greater long-term costs to address these illnesses? Finally, do you agree with CMS statements in the past which have highlighted the importance of face to face interactions among pharmacists and patients with diabetes?**

Answer: Community pharmacies that furnish non-mail order diabetic testing supplies were not required to compete under the Round 1 Rebid competitive bidding program and will not be required to compete under the national mail order program. CMS' rules maintain the ability of patients to have face-to-face counseling with their pharmacists. All contract suppliers under the DMEPOS competitive bidding program are required to meet quality standards and be accredited. These standards, as well as the supplier enrollment standards, require suppliers to educate beneficiaries on the proper use of their equipment and the supplies used with the equipment. As competitive bidding programs are phased in for non-mail order diabetic supplies in the future, or, alternatively, price limits for non-mail order diabetic testing supplies are established and implemented in the future in lieu of such competitions, these programs or price limits will be implemented in a way that preserves access to all necessary items and services in accordance with the quality and supplier enrollment standards.

The Honorable John Shimkus (Transferred to CMS from OIG)

1. **I understand that CMS promulgated a final rule on August 27 prohibiting DMEPOS suppliers from sharing a practice location with another Medicare supplier, like a physician. I am concerned about what this may mean for patient care. While I wholeheartedly support efforts to refine the standards for suppliers in the Medicare program to root out fraud, I remain concerned that this rule may unnecessarily threaten timely patient access to medically necessary items like an ankle fracture boot or a knee immobilizing brace.**

   If a doctor in my district does not choose to be a supplier, will my Medicare beneficiaries still be able to receive these products as they have in the past? It is my understanding that as of September 27th, those patients will have to take a doctor's script, leave the office without the medically necessary product prescribed by the doctor, adding time and inconvenience to the process and possibly leading to further injury. Essentially, we will have a situation where Medicare beneficiaries are treated differently from private pay patients, because they will encounter situations where they have to drive across town for their fracture boot, while the private pay patient is able to receive it in the physician office.

Answer: Medicare beneficiaries in a physician's office can still obtain the required DME at their office. The revision in CMS-6036-F revises standard 29 to prohibit a DMEPOS supplier from sharing a practice location with any other Medicare supplier. However paragraph (29) (ii) (A) advises that the prohibition isn't applicable where a physician or non-physician practitioner furnishes the items to their own patients.

The Honorable Marsha Blackburn (Transferred to CMS from OIG)

1. **You've noted several times that the competitive bidding program has the potential to save taxpayers and beneficiaries money on durable medical equipment, since the bid prices are substantially lower than the amount that Medicare otherwise would pay for DME. But I note that, with respect to diabetes testing supplies, Medicare will actually pay two different prices: one lower, competitively bid price, for blood glucose test strips obtained through the mail; and another, higher price for those same strips purchased at a pharmacy. Beginning January 1, for example, Medicare will pay $15.22 for a box of strips delivered by mail to a senior in Cincinnati, and $37.77 for that very same box of strips obtained by a senior at a Cincinnati pharmacy. Can you explain how seniors and taxpayers benefit by Medicare paying two different prices for the very same box of blood glucose test strips, one of which is 2-1/2 times the other?**

Answer: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized competitive bidding to occur first for high cost, high volume items with the greatest potential for savings. Accordingly, we included mail order diabetic supplies in the initial Round 1. The Medicare Improvements for Patients and Providers Act of 2008 delayed the program and

required CMS to rebid the same items that were included in the initial Round 1 with limited exceptions.

As a result, starting on January 1, 2011, beneficiaries in the 9 Round 1 Rebid areas can choose to have the supplies shipped directly to their homes by a mail order contract supplier at a reduced cost, or pick them up at a pharmacy at a higher cost. We believe that most beneficiaries will elect the savings and choose the mail order contract supplier; however, beneficiaries who want to pick up their supplies at a local pharmacy may choose to do so and pay the higher copayment.

Supplemental Questions for the Record

"Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access"
Before
House Energy & Commerce Health Subcommittee
September 15, 2010

Laurence Wilson, CMS Witness

The Honorable John Barrow

1. **I can envision a scenario where new technologies and treatments could become available in between the three year competitive bidding windows. Many of these supplies tend to evolve rapidly. How do you plan to address the problem of access to new technology that is developed outside the three-year bidding cycle? Will there be a mechanism to reimburse for equipment when the technology becomes available?**

   Answer: Assuming the new technology can be covered by Medicare, payment will depend on whether the item is part of the competitive bidding program. In general, new durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) products described by existing Healthcare Common Procedure Coding System (HCPCS) codes included in the competitive bidding program will be paid at the competitive bidding single payment amount when furnished to beneficiaries who live in competitive bidding areas (CBAs). New DMEPOS technology that is NOT furnished to beneficiaries who live in CBAs or that is NOT described by a HCPCS code included in the program will be paid according to the fee schedule methodology.

   DMEPOS items and services are identified by codes within the HCPCS, and these codes are revised when necessary to reflect changes in technology. In some cases, changes in technology constitute refinements or improvements to existing technologies that can result in an increase or decrease in the costs of furnishing the items. Although there have been gradual improvements in technology for various products such as oxygen concentrators, hospital beds and wheelchairs, the cost of these items generally has not increased as a result. In cases where new technology is developed that goes beyond an improvement or refinement to existing technology, and the new category of items is medically necessary for Medicare beneficiaries, the manufacturers of these items will often request new HCPCS codes. In the event that a new code is added to the HCPCS during a competitive bidding contract period, the new code would be paid according to the fee schedule payment methodology and would not be included in competitive bidding contracts already in effect at the time the code is added.

The Honorable Betty Sutton

1. **How has CMS determined the necessary number of providers to cover a specific bid area so that all beneficiaries are assured of receiving the same standard of care they currently enjoy?**

   Answer: CMS has ensured that access to care for beneficiaries will be ample in several ways.

First, we selected enough suppliers to meet the beneficiary demand throughout the contract period, beginning with the start of the program in January. The methodology we used to calculate future demand was adjusted to ensure that there are excess suppliers for each area. Second, contracts were awarded to a significant number of suppliers already furnishing the product category in the competitive bid areas (CBAs) for which they were awarded contracts. We note that 92% of suppliers offered a contract accepted the contract, indicating that suppliers are eager to be a part of this program at the payment amounts set through the competitive bidding process. Finally, the grandfathering policy allows non-contract suppliers to continue to furnish oxygen and oxygen equipment and rented DME to beneficiaries receiving the equipment on January 1, 2011.

CMS will be monitoring the implementation of competitive bidding closely, and has several enforcement options available to address quality or beneficiary access concerns. If contract suppliers do not maintain quality service for beneficiaries, they may have their contracts terminated. In the event that additional contract suppliers are needed in the future, additional contracts can be awarded as needed to meet demand. Further, if a sufficient number of contract suppliers is not available to meet demand for quality items and services in an area, the program for that product category in that competitive bidding area will be terminated.

2. **In the bid areas, is CMS monitoring the rates of admittance to emergency rooms and re-hospitalizations by beneficiaries who are on home oxygen therapy or enteral nutrition before and after implementation of the bid program?**

   Answer: As competitive bidding is implemented, CMS will do real-time monitoring of claims data to ensure that the program does not result in preventable adverse outcomes. We will be conducting extensive data analysis to monitor the health outcomes of beneficiaries located in a competitive bidding area (CBA). We will be examining claims to determine hospitalization rates before and after the start of the program, changes in the length of stay in a hospital, re-admissions, emergency room visits, and admissions to skilled nursing facilities. We also will be monitoring claims data to ensure beneficiaries have access to needed DMEPOS items.

3. **In the initial nine bid areas, is CMS monitoring the time it takes hospitals to discharge their patients who require home medical equipment to determine if hospitals will experience increased costs due to delayed discharges since those patients will receive equipment from sources other than the hospitals?**

   Answer: Yes – this is part of CMS' real-time monitoring of claims data. In addition to the data analysis identified in our response to question 2, we will be comparing hospital length of stay for beneficiaries before and after the start of the competitive bidding program. We also will compare length of stay in competitive bidding areas (CBAs) with length of stay in comparable non-CBAs. This will allow us to determine if hospitals are experiencing a delay in discharging Medicare beneficiaries in the CBAs.

4. **Has CMS improved its bidder evaluation process this round compared to the 2008 round 1 bid? Also, what specific changes in its analysis of bidders has CMS made to ensure that contractors will be financially viable for the three-year contract period?**

   Answer: We improved the screening process in three significant areas: licensure review; bona fide

bid review; and capacity analysis. All of these improvements will help ensure that bidders will be able to serve bidders for the duration of the contract period, beginning on the first day of the program in January.

Licensure Review: CMS only offered contracts to suppliers that were properly licensed in each State and for each particular service that the suppliers applied for at the time of their bid application. In the initial Round 1, bidders were also required to meet all State licensure requirements prior to submitting a bid. However, there were concerns that some of the 2008 contract suppliers did not have all required State licenses. To alleviate these concerns in the Round 1 Rebid, CMS conducted a rigorous, comprehensive verification of bidder's compliance with all applicable State licensure requirements early in the bid evaluation process. This involved checking supplier licenses already on file with Medicare, working directly with States to confirm the licensure status of specific bidders, and working directly with suppliers when necessary to verify that they meet the licensure requirements.

Bona Fide Bids: Under the DMEPOS competitive bidding program, only suppliers that submitted "bona fide" bids may be awarded contracts. Accordingly, all bids submitted were screened to ensure that they represent a rational, sustainable, and feasible payment for furnishing the item. In instances where a bid was identified through the bona fide bid screening process as extremely low in relation to other bids, CMS further evaluated that bid to confirm that the supplier could furnish the item at the listed bid amount. In so doing, CMS reviewed additional information beyond that collected in 2008, such as supplier rationales that support documentation like manufacturer's invoices. Suppliers that submitted bids that were not found to be "bona fide" after review of certain information were not awarded contracts for the applicable product category and CBAs; only bona fide bids were included in the calculation of the single payment amounts.

Capacity and Expansion Plans: CMS improved its capacity and expansion plan review for the Round 1 Rebid after consultation with the Program Advisory and Oversight Committee (PAOC). The PAOC raised initial concerns that bidders new to an area or product category, or reporting high capacity figures, might not be able to ramp up to their reported capacity in time to meet the projected demand at the beginning of the contract period.

To address these concerns, CMS utilized a "capacity ramp up" analysis to review what percentage of demand in 2011 would be met by experienced suppliers reporting no expansion or a modest expansion in capacity and what percentage of demand in 2011 would be met by new suppliers or experienced suppliers reporting more than a modest expansion in capacity. In any case, where this second category of suppliers was counted on to meet any portion of projected demand in 2011, the expansion plans of these suppliers were scrutinized with particular emphasis on liquid assets and available credit needed to expand their capacity. If this information did not substantiate the supplier's estimated capacity, CMS adjusted the capacity of the supplier to the supplier's historic level for the purpose of selecting enough contract suppliers to meet expected demand. This capacity analysis had no impact on whether or not a contract was awarded and was limited to an analysis of what supplier capacity could be justified. Further, as in the initial Round 1, in order to ensure appropriate capacity planning and market competition between DMEPOS suppliers in each area, CMS did not allow any one supplier to account for more than 20 percent of the market. Finally, it is important to note that CMS' projected demand calculations for rented items of durable medical equipment (DME) in 2011 was not discounted in any way even though we predict that a

large number of these items will be furnished by noncontract, grandfathered suppliers. In order to ensure sufficient capacity to serve all beneficiary needs, contract supplier capacity was reviewed as if 100 percent of demand must be met by the winning suppliers.

5. **How many bids were eliminated because of low or unrealistic fees? How many bids and suppliers were disqualified in total, and as a percent of the total?**

   Answer: The DMEPOS competitive bidding program final rule requires that each bidder submit a bona fide bid as specified in the request for bids. In other words, each bid amount must be a rational, feasible, and sustainable payment for furnishing the item. If a supplier submitted a non-bona fide bid for a single item in a product category, then the supplier was eliminated from competition for that product category.

   A total of 102 out of 6,215 bids (1.64%) were excluded as being non-bona fide bid amounts. A total of 4,891 bids and 638 suppliers were not successful; most of these suppliers were not successful because their bids were above the winning range.

6. **How many DME providers that were initially offered contracts chose not to sign contracts?**

   Answer: Ninety-two percent (92%) of suppliers offered contracts accepted those contracts.

7. **Has anyone at CMS assessed the potential impact on the economy related to job losses that are expected under this so-called competitive bidding program?**

   Answer: As we look at the DMEPOS suppliers in the competitively bid areas, Medicare is not a significant source of income for most of these suppliers., During 2009, only about 20 percent of the suppliers in the nine Round 1 Rebid areas had more than $10,000 in allowed Medicare charges, and only 11 percent of suppliers in the nine Round 1 Rebid areas submitted more than $50,000 in allowed Medicare charges. This data seems to indicate that most DMEPOS suppliers have other sources of income and that Medicare is not responsible for the majority of their revenue.

   While it is true that after the program begins suppliers that do not receive contracts generally cannot receive Medicare payment for competitively bid DMEPOS items, there are still opportunities for these suppliers to continue their businesses. Noncontract suppliers may choose to be grandfathered suppliers for existing customers to whom they were providing certain rented items or oxygen equipment prior to the competitive bid program. Also, any Medicare supplier (regardless of whether they received a contract) may provide, and bill for, repairs and replacement parts needed to repair beneficiary owned equipment. And there is nothing to prohibit noncontract suppliers from becoming subcontractors for delivery and setup, repair, and inventory services for contract suppliers in these areas.

   We do not believe that implementation of the competitive bidding program will result in significant lost jobs for several reasons. First, as noted above, many suppliers that do not become contract suppliers will be able to continue their businesses. Also, contract suppliers may need to expand their businesses to meet beneficiary demand in a competitive bidding area, which would create local jobs. Contract suppliers may elect to hire staff from non-contract suppliers or decide to acquire noncontract suppliers. Further, Medicare's scope of benefits and beneficiary demand for

DMEPOS items are not being changed by the program, so the contract suppliers will need to employ sufficient staff to meet demand.

8. **Since there is very little time between the end of round 1 and the beginning of round 2, can you provide more specific details as to how CMS plans to make improvements and implement changes to the bid program before round 2 begins?**

Answer: We have made substantial improvements to the program since its delay in 2008 and have already learned much from the Round 1 Rebid. For example, our bidder education program and improved on-line bid submission system worked very smoothly. We were very pleased with results of these improvements and believe they can be easily adapted to include more areas.

CMS has strong tools in place to begin monitoring and evaluating the program from day one. CMS will be seeking feedback from beneficiaries through consumer satisfaction surveys conducted before and after the rollout of the program. CMS will provide a local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen, who will closely monitor transition activities, conduct a local assessment of supplier activities, analyze trends, and identify and address any emerging issues. There also will be an inquiry and formal complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues. In addition, contract suppliers are responsible for submitting quarterly reports identifying the brands of products they furnish, which will be used to inform beneficiaries and caregivers and help CMS evaluate supplier compliance with contract terms. CMS will also conduct real-time claims analysis to identify utilization trends, monitor beneficiary access, address aberrancies in services, and target potential fraud and abuse. Finally, CMS has appointed a Competitive Acquisition Ombudsman who will respond to complaints and inquiries from beneficiaries and suppliers about the application of the program and will issue an annual Report to Congress. We will be evaluating the results carefully and working closely with the Program Advisory and Oversight Committee to identify and resolve any issues.

CMS is committed to beginning the Round 2 competition in 2011 as mandated by law. We are confident that we have the infrastructure in place for a successful Round 2.

GAO
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United States Government Accountability Office
Washington, DC 20548

November 2, 2010

The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: Responses to Question for the Record - GAO Testimony Entitled *MEDICARE: CMS Has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid*

Dear Chairman Waxman,

This letter responds to your October 20, 2010 request that we address for the record questions related to the Subcommittee's September 15, 2010 hearing entitled "Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access." Our response to the question, which is in the enclosure, is based on our previous work and knowledge of the subjects raised by the question.

If you have any questions about the letter or need additional information, please contact me on (202) 512-7114 or at kingk@gao.gov or contact Martin Gahart on (202) 512-3596 or at gahartm@gao.gov.

Sincerely yours,

Kathleen M. King

Kathleen King
Director, Health Care

Enclosure

Enclosure I

Enclosure I

Response to Post-Hearing Question for the Record
Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost and Access

Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
September 15, 2010

Question for Kathleen King
Director, Health Care
U.S. Government Accountability Office

Question for the Record Submitted by the Honorable Marsha Blackburn

1. **You've noted several times that the competitive bidding program has the potential to save taxpayers and beneficiaries money on durable medical equipment, since the bid prices are substantially lower than the amount that Medicare otherwise would pay for DME. But I note that, with respect to diabetes testing supplies, Medicare will actually pay two different prices: one lower, competitively bid price, for blood glucose test strips obtained through the mail; and another, higher price for those same strips purchased at a pharmacy. Beginning January 1, for example, Medicare will pay $15.22 for a box of strips delivered by mail to a senior in Cincinnati, and $37.77 for that very same box of strips obtained by a senior at a Cincinnati pharmacy. Can you explain how seniors and taxpayers benefit by Medicare paying two different prices for the very same box of blood glucose test strips, one of which is 2-1/2 times the other?**

   There are two different prices for diabetic supplies because mail-order diabetic supplies are one of the nine product categories included in the Centers for Medicare & Medicaid Services (CMS) competitive bidding program (CBP). Diabetic supplies sold at a pharmacy are not included in CBP and are still paid under the Medicare fee schedule. Medicare beneficiaries in the Cincinnati competitive bidding area will have an incentive to purchase their diabetic supplies through mail order to take advantage of the CBP savings. Beneficiaries' 20 percent Medicare coinsurance payment will be less for mail-order supplies than if the supplies are purchased at a pharmacy. A beneficiary would save $3.64 by purchasing diabetic supplies by mail-order; the savings is the difference between the beneficiary coinsurance for the Medicare fee schedule payment of $33.42 in Ohio and its $6.68 coinsurance, and the $15.22 CBP mail order payment in Cincinnati and its $3.04 coinsurance.

   The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to phase in the competitive bidding program (CBP) beginning with selected durable medical equipment (DME) items in some of the largest metropolitan statistical areas. CMS generally chose DME product categories by selecting items with the highest volume and highest cost or those with the largest Medicare savings potential. CMS determined that diabetic supplies delivered to Medicare beneficiaries by mail-order

was one such category. As one of the largest metropolitan statistical areas, the Cincinnati-Middletown (Ohio, Kentucky, and Indiana) competitive bidding area was included in both CBP's round 1 and the round 1 rebid. Suppliers submitting bids in CBP's round 1 and the round 1 rebid had to submit bid prices that were at or less than the current Medicare fee schedule payment for the DME items included in CBP.

The CBP's competitively determined Medicare payments—the single payment amounts—are determined for each competitive bidding area and differ among the areas. In the CBP round 1 rebid, the items in the mail-order diabetic supplies product category had the largest reduction, with the difference between the single payment amounts and the Medicare fee schedule averaging 56 percent.

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